UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

FEDERAL TRADE COMMISSION,

STATE OF ILLINOIS, and

STATE OF MINNESOTA,

Plaintiffs,

v.

GTCR, LLC,
GTCR BC HOLDINGS, LLC, and
SURMODICS, INC.,

Defendants.

Case No. 1:25-cv-02391

Hon. Jeffrey I. Cummings

PLAINTIFFS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

TABLE OF CONTENTS

PLA	IN	TIFFS' PROPOSED FINDINGS OF FACT	1
I.		INTRODUCTION	1
II.		THE PARTIES, PROPOSED ACQUISITION, AND PROCEDURAL HISTORY	5
III.		HYDROPHILIC COATINGS ARE ESSENTIAL FOR LIFESAVING INTERVENTIONAL MEDICAL DEVICES	6
IV.		GTCR INTENDS TO COMBINE BIOCOAT AND SURMODICS TO ADVANCE ITS "CONSOLIDATION PLAY" IN THE OUTSOURCED HYDROPHILIC COATINGS MARKET	7
V.		THE RELEVANT PRODUCT MARKET IS OUTSOURCED HYDROPHILIC COATINGS	9
a.		Brown Shoe Practical Indicia Establish a Relevant Product Market of Outsourced Hydrophilic Coatings	9
	i.	Hydrophilic Coatings Have Peculiar Characteristics and Uses	9
	ii.	Industry Recognition of the Outsourced Hydrophilic Coatings Market	10
	iii.	Hydrophilic Coatings Are Supplied by Specialized Vendors	.11
	iv.	Hydrophilic Coatings Pricing is Distinct	13
	v.	Hydrophilic Coating Customers Are Sensitive to Price Changes	13
	vi.	Hydrophilic Coating Customers are Distinct	15
	vii	The Relevant Product Market Includes Both UV-cured and Thermal-cured Hydrophilic Coatings	
	vii	ii. Hydrophobic Coatings are Not Reasonably Interchangeable with Hydrophilic Coatings	18
	ix.	In-House and Outsourced Hydrophilic Coatings are Not Reasonably Interchangeable	20
b.		Outsourced Hydrophilic Coatings Satisfies the Hypothetical Monopolist Test	22
VI.		THE RELEVANT GEOGRAPHIC MARKET IS THE UNITED STATES	23
VII.		MARKET STRUCTURE AND CONCENTRATION	23
a.		Biocoat and Surmodics are the Two Largest Hydrophilic Coating Suppliers	23
b.		Other Suppliers Have Substantially Smaller Market Shares	25
	i.	Harland	25
	ii.	DSM	26
c.		Remaining Hydrophilic Coating Suppliers Have Substantially Smaller Presences and Lac Key Capabilities	

VIII.	THE PROPOSED ACQUISITION WILL SUBSTANTIALLY LESSEN COMPETITION	29
a.	The Proposed Acquisition Results in Presumptively Illegal Market Shares and Concentration Levels	29
i.	Revenue Is a Reliable Measure of Market Shares in This Industry	30
ii.	Market Share Calculations Based on FDA Data, When Performed Correctly, are in Accord	32
b.	The Proposed Acquisition Would Eliminate Head-to-Head Competition	34
i.	Customers View Biocoat and Surmodics as Direct Competitors	34
ii.	Defendants Routinely Identify Surmodics and Biocoat as Key, Head-to-Head Competitors	35
iii	. Coatings Providers Confirm Surmodics and Biocoat Compete	38
iv	. Biocoat and Surmodics Compete to Coat the Same Medical Devices	39
c.	Competition Between Biocoat and Surmodics Has Led to Decreased Pricing and Increase Innovation.	
i.	Biocoat and Surmodics Compete on Price	40
ii.	Biocoat and Surmodics Compete on Services.	41
iii	. Biocoat and Surmodics Compete to Innovate Coating Technologies	43
d.	The Proposed Acquisition Has Already Lessened Competition	44
IX.	DEFENDANTS' PROPOSED REMEDY DOES NOT OFFSET THE LIKELY COMPETITIVE HARM OF THE PROPOSED ACQUISITION	46
a.	The Incumbent Hydrophilic Coating Supplier Has an Advantage When Competing for N Devices from Existing Customers	
b.	The "License Back" Provision Immediately Hinders Integer's Ability to Compete and Differentiate Itself from the Merged Firm.	49
c.	Integer Previously Abandoned Its Own Hydrophilic Coating; the Divestiture Provides Neither the Assets nor the Incentives for Integer to Succeed Now	
d.	Integer's Show Lack of Competition from Post-Divestiture Integer	54
e.	The Proposed Partial Divestiture Excludes Key Assets, Employees, and Facilities That an Necessary to a Divestiture Buyer's Success	
f.	Post-Divestiture, Integer Would Be Reliant on Biocoat and Surmodics, With Whom It Is Expected to Compete	61
g.	Scale Isn't Enough – the Fact that Integer is a Large Company Does Not Automatically Position It for Success in Hydrophilic Coatings	64
X.	DEFENDANTS OTHERWISE FAIL TO REBUT PLAINTIFFS' PRIMA FACIE CASE	67

a.	Entry or Expansion is Unlikely to be Timely or Sufficient to Preserve Competition	67
b.	Defendants Fail to Demonstrate Any Cognizable Efficiencies	69
XI.	EQUITIES FAVOR A PRELIMINARY INJUNCTION	70
PLAI	NTIFFS' PROPOSED CONCLUSIONS OF LAW	70
I.	Legal Standard	70
a.	Section 7 of the Clayton Act	70
b.	Standard for Injunctive Relief (Section 13(b) of the FTC Act)	71
c.	Burden-Shifting Framework	73
d.	Evidentiary Value of Ordinary Course Documents	75
II.	Relevant Antitrust Market	76
a.	Product Market	76
i.	Brown Shoe Factors	79
ii	. Hypothetical Monopolist Test	84
b.	Geographic Market	85
III.	Proposed Acquisition's Effect on Competition	86
a.	The Proposed Acquisition Is Presumptively Illegal	86
b.	The Proposed Acquisition Eliminates Substantial Head-to-Head Competition	90
IV.	Defendants Cannot Rebut Plaintiffs' Prima Facie Case	91
a.	The Proposed Partial Divestiture Does Not Address the Acquisition's Anticompetitive	
	Harm	
i.		
ii	•	92
b.	Entry And Expansion Must Be Timely, Likely, and Sufficient to Counteract the Acquisition's Anticompetitive Effects	98
c.	Efficiencies Must Be Verifiable and Merger Specific	98
V.	Equities Favor a Preliminary Injunction	99

TABLE OF AUTHORITIES

Cases

Beatrice Foods Co. v. FTC, 540 F.2d 303 (7th Cir. 1976)
Brown Shoe Co. v. United States, 370 U.S. 294 (1962)passim
Chi. Bridge & Iron Co. v. FTC, 534 F.3d 410 (5th Cir. 2008)
FTC v. Advoc. Health Care Network, 841 F.3d 460 (7th Cir. 2016)passim
FTC v. Advoc. Health Care, 2017 WL 1022015 (N.D. III. Mar. 16, 2017)
FTC v. Arch Coal, Inc., 329 F.Supp.3d 109 (D.D.C. 2004)
FTC v. Cardinal Health, Inc., 12 F.Supp.2d 34 (D.D.C. 1998)
FTC v. CCC Holdings Inc., 605 F.Supp.2d 26 (D.D.C. 2009)
FTC v. Dean Foods Co., 384 U.S. 597 (1966)
FTC v. Elders Grain, Inc., 868 F.2d 901 (7th Cir. 1989)
FTC v. Exxon Corp., 636 F.2d 1336 (D.C. Cir. 1980)
FTC v. H.J. Heinz Co., 246 F.3d 708 (D.C. Cir. 2001)passim
FTC v. IQVIA Holdings, Inc., 710 F.Supp.3d 329 (S.D.N.Y. 2024)passim
FTC v. Kroger Co., 2024 WL 5053016 (D. Or. Dec. 10, 2024)
FTC v. Microsoft Corp., 681 F.Supp.3d 1069 (N.D. Cal. 2023)
FTC v. OSF Healthcare Sys., 852 F.Supp.2d 1069 (N.D. Ill. 2012)
FTC v. Peabody Energy Corp., 492 F.Supp.3d 865 (E.D. Mo. 2020)
FTC v. Penn State Hershey Med. Ctr., 838 F.2d 327 (3rd Cir. 2016)
FTC v. PPG Indus., Inc., 798 F.2d 1500 (D.C. Cir. 1986)
FTC v. ProMedica Health, 2011 WL 1219281 (N.D. Ohio March 29, 2011)
FTC v. RAG-Stiftung, 436 F.Supp.3d 278 (D.D.C. 2020)

FTC v. Sanford Health, 926 F.3d 959 (8th Cir. 2019)	98
FTC v. Staples, Inc., 970 F. Supp. 1066 (D.D.C. 1997)	passim
FTC v. Staples, Inc., 190 F.Supp.3d 100 (D.D.C. 2016)	74, 79, 83, 92
FTC v. Surescripts, LLC, 665 F.Supp.3d 14 (D.D.C. 2023)	79
FTC v. Sysco Corp., 113 F.Supp.3d 1 (D.D.C. 2015)	passim
FTC v. Tapestry, Inc., 755 F.Supp.3d 386 (S.D.N.Y. 2024)	passim
FTC v. Tempur Sealy Int'l, Inc., 768 F.Supp.3d 787 (S.D. Tex. 2025)	71, 74, 80
FTC v. Tronox Ltd., 332 F.Supp.3d 187 (D.D.C. 2018)	78, 79, 82, 92
FTC v. Univ. Health Inc., 938 F.2d 1206 (6th Cir. 1991)	87, 88
FTC v. Warner Comm'cns, 742 F.2d 1156 (9th Cir. 1984)	100
FTC v. Whole Foods Mkt., Inc., 548 F.3d 1028 (D.D.C. 2008)	77, 90
FTC v. Wilh. Wilhelmsen Holding ASA, 341 F.Supp.3d 27 (D.D.C. 2018)	83, 88
Hosp. Corp. of Am. v. FTC, 807 F.2d 1381 (7th Cir. 1986)	71, 74
Illumina, Inc. v. FTC, 88 F.4th 1036 (5th Cir. 2023)	80, 92
In re Dealer Mgmt. Sys. Antitrust Litig., 581 F.Supp.3d 1029 (N.D. Ill. 2022)	85
McWane, Inc. v. FTC, 783 F.3d 814 (11th Cir. 2015)	85
ProMedica Health Sys., Inc. v. FTC, 749 F.3d 559 (6th Cir. 2014)	77, 90
Starbucks Corp. v. McKinney, 602 U.S. 339 (2024)	73
Tevra Brands LLC v. Bayer HealthCare LLC, 2024 WL 2261946 (N.D. Cal. May 16, 2024)	85
United States v. Aetna Inc., 240 F.Supp.3d 1 (D.D.C. 2017)	passim
United States v. Aluminum Co. of Am., 377 U.S. 271 (1964)	83
United States v. Archer-Daniels-Midland Co., 866 F.2d 242 (8th Cir. 1988)	84
United States v. Baker Hughes, Inc., 908 F.2d 981 (D.C. Cir. 1990)	73

United States v. Bazaarvoice, Inc., 2014 WL 203966 (N.D. Cal. Jan. 8, 2014)	85
United States v. Bertelsmann SE & Co., 646 F.Supp.3d 1 (D.D.C. 2022)	77, 89, 91
United States v. Blue Bell, Inc., 395 F.Supp. 538 (M.D. Tenn. 1975)	91
United States v. Continental Can Co., 378 U.S. 441 (1964)	78, 81
United States v. E.I. du Pont de Nemours & Co., 353 U.S. 586 (1957)	71
United States v. Energy Sols., Inc., 265 F.Supp.3d 415 (D. Del. 2017)	88, 89
United States v. Franklin Elec. Co., 130 F.Supp.2d 1025 (W.D. Wis. 2000)	74
United States v. Gen. Dynamics Corp., 415 U.S. 486 (1974)	
United States v. H&R Block, Inc., 833 F.Supp.2d 36 (D.D.C. 2011)	passim
United States v. Marine Bancorp., Inc., 418 U.S. 602 (1974)	73
United States v. Mfrs. Hanover Trust Co., 240 F.Supp.867 (S.D.N.Y. 1965)	90
United States v. Phila. Nat'l Bank, 374 U.S. 321 (1963)	86
United States v. Rockford Mem'l Corp., 898 F.2d 1278 (7th Cir. 1990)	82
United States v. Sungard Data Sys., Inc. 172 F.Supp.2d 172 (D.D.C. 2001)	81, 82
United States v. UnitedHealth Group Inc., 630 F.Supp.3d 118 (D.D.C. 2022)	75, 93, 94
United States v. Visa U.S.A., Inc., 163 F.Supp.2d 322 (S.D.N.Y. 2001)	81
United States v. Visa U.S.A., Inc., 344 F.3d 229 (2d Cir. 2003)	81
Statutes	
Section 13(b) of the FTC Act, 15 U.S.C. § 53(b)	71, 72, 73
Section 7 of the Clayton Act, 15 U.S.C. § 18	passim
Other Authorities	
U.S. Dep't of Justice & Fed. Trade Comm'n, Merger Guidelines (2023)	86, 87, 90

PLAINTIFFS' PROPOSED FINDINGS OF FACT1

I. INTRODUCTION

The Court should preliminarily enjoin GTCR, LLC and GTCR BC Holdings, LLC's (together, "GTCR") proposed acquisition of Surmodics, Inc. ("Surmodics"). The evidentiary hearing established three dispositive facts that conclusively demonstrate the need for a preliminary injunction. *First*, Biocoat, Inc. ("Biocoat") and Surmodics are the two largest competitors today in the highly concentrated outsourced hydrophilic coatings market. *Second*, head-to-head competition between Biocoat and Surmodics results in price, quality, service, and innovation competition that meaningfully benefits medical device manufacturers and, ultimately, the health and well-being of patients. *Finally*, Defendants' proposed partial divestiture to Integer would not effectively remedy the competition lost from GTCR's acquisition of Surmodics.

Defendants' testimony and ordinary course documents confirm that GTCR acquired Biocoat in 2022 as a "" and that GTCR is pursuing a deliberate "consolidation play" in the top-heavy outsourced hydrophilic coatings industry. Biocoat and Surmodics are the #1 and #2 players in this industry, where customer lock-in and high switching costs give Biocoat and Surmodics enduring power as the dominant suppliers. Defendants' own testimony and internal documents

; Ankeny (Harland) 215:14-20

(Surmodics is Harland's biggest competitor, followed by Biocoat). Customers are almost uniformly agnostic as to curing method. *See* PFOF, *infra* ¶ 40 (collecting customer testimony);

¹ All admitted exhibits and deposition designations were provided to the Court by the Parties on September 10, 2025, via flash drive. All other fact citations are to the Transcript of the Preliminary Injunction Evidentiary Hearing.

² See Proposed Findings of Fact ("PFOF"), infra ¶¶ 67-74.

³ *See* PFOF, *infra* ¶¶ 96-140.

⁴ *See* PFOF, *infra* ¶¶ 141-214.

⁷ PX1028 at 007, 033; see also

reveal that Biocoat and Surmodics view each other as fierce competitors⁸ for both new and existing customers and consider themselves to be the top two competitors in today's market.⁹

,¹⁰ while a

,¹⁰ while a

and most senior executives have repeatedly identified Biocoat as a " or "top" competitor in recent internal communications.¹²

Nearly every customer and competitor testified that Biocoat and Surmodics compete head-to-head and are the largest, most significant competitors in the market today.¹³ In contrast, Defendants failed to produce a single customer or competitor who testified that Biocoat and Surmodics are not the top hydrophilic coatings competitors.

Defendants ask this Court to disregard the voluminous evidence of their dominance and claim, without support, that revenue is not an accurate measure of market share in this industry. To the contrary, revenue-based market shares closely align with Defendants' own documents and testimony from market participants who consistently describe Biocoat and Surmodics as the market leaders *today*—not just for existing devices, but for new opportunities. ¹⁴ Ordinary course documents and testimony from coatings customers, competitors, and Defendants themselves show that industry

⁸ See PFOF, infra ¶¶ 114-21.

⁹ See, e.g., PFOF, infra ¶¶ 114-21. See also

¹⁰ PX1294 at 015 (Biocoat Positioning Workshop (Feb. 2025), labeling Harland and "Company M" (Surmodics) as Biocoat's "Primary Competitors" in "The hydrophilic coatings solutions marketplace").

¹² See see also PFOF infra ¶ 117...

¹³ See PFOF, infra ¶¶ 72-74, 112.

¹⁴ *See* PFOF, *infra* ¶¶ 101-104.

participants rely on annual revenue data in analyzing the current market and their market share.¹⁵ Established case law confirms that revenues are the best metric to assess the relative competitive strength of firms in a relevant market.¹⁶ The facts and law make clear that Biocoat and Surmodics are the two most significant players in the market—by revenue and by reputation among market participants. The proposed acquisition will extinguish the rivalry that currently exists between Biocoat and Surmodics, lead to a combined, presumptively anticompetitive 60% market share, and substantially lessen competition to the detriment of patients, doctors, and medical device firms.

Evidence presented at trial demonstrates that Defendants' proposed partial divestiture to Integer will not restore this lost competition. 17 Defendants' proposal includes only """ of Biocoat's business, 18 consisting of an undifferentiated thermal-cured offering Integer must license back to Biocoat and less than in potential business for a UV-cured coating that Biocoat CEO Chip Hance admitted

19 Integer also faces steep hurdles to becoming a viable competitor to the merged firm. Integer's

20 and only

21 Integer may struggle to attract new business, as customers are reluctant to work with CDMOs like Integer or source their coatings from new suppliers who have no reputation for coatings in the market. 22 These are obstacles that Integer's scale will not solve. Indeed, it took

¹⁵ PFOF, *infra* ¶¶ 101-104.

¹⁶ Proposed Conclusions of Law ("PCOL"), *infra* ¶ 294-97.

¹⁷ PX4013 (Fix Rebuttal) ¶ 221.

[;] see generally PFOF, infra \P 141-214.

Wong 1632:22-1633:1 (admitting brand reputation can influence the coating selection); PX4013 (Fix Rebuttal) ¶ 211 (noting that the license back to Biocoat means Integer likely doesn't have "much of a shot with existing major OEMs to secure any meaningful business"); see PFOF, infra, ¶ 167.

DSM—a company considerably larger than Integer—five to six years to enter the U.S. market even though DSM already had 15 years' experience in hydrophilic coatings.²³ Even with the best intentions to compete, Andrew Senn, President of Integer's Cardio and Vascular Division, acknowledged that Integer's tentative plans for the divestiture are not guaranteed, as they are dependent on help from the merged firm, and Integer will make internal resource decisions based on the profitability of the opportunity.²⁴

25 26

This is not a remedy intended to create a real rival to the combined firm. And that is the point: a formidable rival would undermine GTCR's "consolidation play" and the return on their investment. Defendants have been candid that this acquisition is about the "institutions and individuals who invest in the companies" Surmodics and Biocoat.²⁷ With no demonstrated efficiencies from the acquisition, the most straightforward path to benefit Defendants is to raise prices, reduce innovation, and cut customer support. This is not speculation—these are the well-recognized consequences of diminished competition in a highly concentrated market and precisely the harms the antitrust laws are designed to prevent.

This acquisition is not about improving patient care, spurring innovation, or enhancing manufacturing efficiencies. GTCR Managing Director, Luke Marker admitted the deal is "not

²³ PFOF, *infra* ¶ 206; Petra (DSM) 309:7-8.

²⁴ PFOF, infra ¶¶ 165, 196-204.

²⁶

²⁷ Defendants' Closing Argument 1978:2-3.

predicated on a bunch of synergies[.]"²⁸ Defendants' failure to offer any procompetitive benefit shows this deal is all about control—specifically, consolidating the top two players in a highly concentrated market to secure dominant market share and extract higher returns for investors. The law presumes such a transaction is unlawful, and the evidence here more than justifies that presumption.

II. THE PARTIES, PROPOSED ACQUISITION, AND PROCEDURAL HISTORY

- 1. GTCR is a private equity firm that provides management services, including advisory services, to affiliated funds that invest in portfolio companies.²⁹ Investment committees make investment decisions on behalf of GTCR funds; each fund has its own investment committee.³⁰



4. Surmodics, a publicly traded company founded in 1979,³⁵ is the largest supplier of outsourced hydrophilic coatings for medical devices in the United States.³⁶ Surmodics also sells

²⁸ Marker (GTCR) 873:17-24 (discussing PX1611 at 001).

²⁹ Marker (GTCR) 868:22-869:7.

³⁰ Marker (GTCR) 871:11-18.

³¹ PX4000 (Fix Report) ¶ 37, 39; Marker (GTCR) 878:13-879:13; Moran (Biocoat) 779:9-11;

³² Hergenrother (Biocoat) 1420:14-20; Moran (Biocoat) 779:15-20.

³³ Moran (Biocoat) 779:12-14.

Wioraii (Biocoat) 779.12-14

³⁵ Maharaj (Surmodics) 1020:16-19.

³⁶ PX4000 (Fix Report) ¶ 114.

vascular intervention medical devices and operates other business units.³⁷

- 5. Surmodics' performance coatings business generates revenue primarily through the sale of coatings reagents, licensing and royalties based on the use of Surmodics' intellectual property, and development and coating services for customers.³⁸ For fiscal year 2024, Surmodics' revenue from performance coating royalties and license fees totaled \$37.4 million.³⁹
- 6. GTCR announced its acquisition of Surmodics on May 29, 2024.⁴⁰ On March 6, 2025, the FTC initiated an administrative proceeding to permanently enjoin the acquisition and filed this action seeking a preliminary injunction to maintain the status quo. On April 16, 2025, the FTC filed an amended complaint in which the Attorneys General of Illinois and Minnesota joined the FTC in seeking a preliminary injunction, and GTCR, LLC was named as a defendant in this action.
- 7. On April 24, 2025, GTCR provided an initial term sheet to the FTC related to a proposed remedy; a divestiture buyer was not selected until June 4, 2025, when GTCR confirmed Integer as the divestiture buyer. 41 GTCR and Integer executed a proposed divestiture agreement on July 29, 2025. 42 On July 30, 2025, GTCR provided to Plaintiffs the executed Asset Purchase Agreement ("APA") and ancillary documents related to the proposed divestiture transaction, all of which is contingent on the closing of the proposed acquisition. 43 Under the APA, Integer is contractually obligated to cooperate with Defendants in opposing this litigation. 44

III. HYDROPHILIC COATINGS ARE ESSENTIAL FOR LIFESAVING INTERVENTIONAL MEDICAL DEVICES

³⁷ Maharaj (Surmodics) 1018:24-1020:19; DX-208 at 006 (Surmodics 2024 10-K).

³⁸ Maharaj (Surmodics) 1022:12-22.

³⁹ DX-208 at 040 (Surmodics 2024 10-K).

⁴⁰ de Freitas (Biocoat) 552:25-553:3.

⁴¹ Marker (GTCR) 895:17-897:15.

⁴² Marker (GTCR) 903:23-904:3.

⁴³ Marker (GTCR) 903:23-904:3:

⁴⁴ See DX-002 at 017, § 3.03(d) (APA between Biocoat and Integer, July 29, 2025) ("... the Buyer shall use reasonable best efforts to cooperate with the Seller in opposing (including by cooperating in litigation) [the preliminary injunction action]...").

- 8. Hydrophilic coatings add lubricity to the surface of a minimally invasive medical device to make it easier to navigate the device through the body.⁴⁵ Medical devices that use hydrophilic coatings prevent and treat life-threatening illnesses, including blood clots and strokes.⁴⁶
- 9. Jared Hutar, co-founder and CEO of Piraeus, a company that "design[s] and build[s] neurovascular devices that treat a variety of brain diseases," explained that Piraeus cannot get a hydrophilic coating's lubricious property from any other coating. 48
- 10. Hydrophilic coatings are important for patient safety: "
- ."⁴⁹ If a minimally invasive medical device fails to reach its target in the body through the blood vessels, the patient may not receive the therapeutic intervention that they need.⁵⁰
- 11. Lubricity, durability, and particulate count are important measures of the performance of a hydrophilic coating.⁵¹ Particulate count—a measure of the amount of hydrophilic coating that flakes off the device during a procedure—is especially important and "

,,52

IV. GTCR INTENDS TO COMBINE BIOCOAT AND SURMODICS TO ADVANCE ITS "CONSOLIDATION PLAY" IN THE OUTSOURCED HYDROPHILIC COATINGS MARKET

12. GTCR advertises on its public website a philosophy called "The Leader's Strategy," which

⁴⁵ Ankeny (Harland) 202:3-24;

⁴⁶ Stern (Contego) 966:5-9.

⁴⁷ Hutar (Piraeus) 395:21-24.

⁴⁸ Hutar (Piraeus) 403:5-14; PFOF, *infra* ¶¶ 18-21.

[;] Ankeny (Harland) 202:25-203:14.

Martin (Maduro) 683:20-23; *see* Eccles (Scientia) 468:24-469:5 ("Q. Could patients be harmed if Scientia's devices did not have a hydrophilic coating on them? A. Yes, absolutely. A. Would it be more difficult for doctors to perform . . . procedures if Scientia's devices did not have a hydrophilic coating on them? A. Yes."). ⁵¹ de Freitas (Biocoat) 519:3-12 (Biocoat customers seek high lubricity and durability and low particulate counts); Ventura (Surmodics) 384:6-17 ("

[&]quot;); Ankeny (Harland) 207:3-208:3 (describing durability and particulate count).

GTCR describes in part as "partner[ing] with strong incumbent management teams to provide them capital to execute transformational opportunities like acquiring a significant competitor." ⁵³

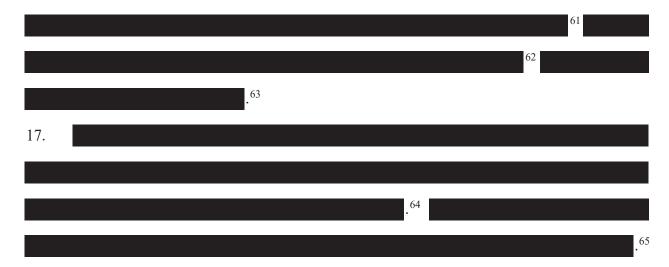
13. GTCR acquired Biocoat in November 2022 as a "secute an "excellent consolidation play"⁵⁵ in the hydrophilic coatings industry.



15. In January 2023, less than three months after GTCR's acquisition of Biocoat, GTCR and Biocoat's Board acknowledged that "[t]o achieve our desired returns [for Biocoat], significant M&A is a necessity." In February 2023,

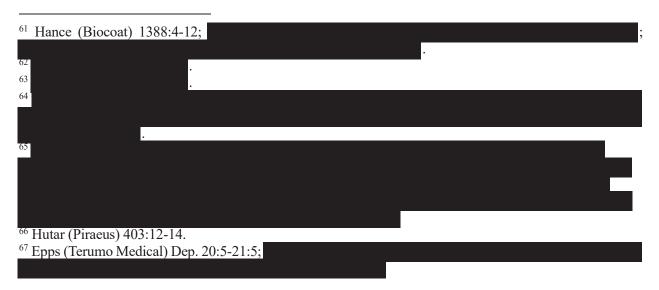


⁵³ PX6020 (GTCR, The Leaders Strategy); Marker (GTCR) 869:14-870:10.



V. THE RELEVANT PRODUCT MARKET IS OUTSOURCED HYDROPHILIC COATINGS

- a. *Brown Shoe* Practical Indicia Establish a Relevant Product Market of Outsourced Hydrophilic Coatings
 - i. Hydrophilic Coatings Have Peculiar Characteristics and Uses
- 18. Hydrophilic coatings have peculiar characteristics that differentiate them from other types of medical coatings, particularly a level of lubricity that far surpasses other types of lubricious medical coatings. ⁶⁶ Hydrophilic coatings have long been widely recognized by medical device manufacturers as "the gold standard" for interventional devices. ⁶⁷
- 19. The narrower the target location for a medical device, the more likely the device will require



a hydrophilic coating to navigate the torturous curves of the body's vasculature.⁶⁸ As a result, devices used in cardiovascular and peripheral vascular procedures "tend to favor" and "need" hydrophilic coatings due to hydrophilic coatings' highly lubricious properties.⁶⁹

20. Almost all minimally invasive neurovascular devices, such as neurovascular catheters, use hydrophilic coatings to effectively reduce friction between the device and vessel walls as the device navigates into the brain. Will Eccles, VP of Research and Development at Scientia Vascular, testified that he is "not aware of any technology that would be lubricious enough to be able to access the brain outside of a hydrophilic coating."

72

21. Other medical device coatings that provide some degree of lubricity, such as hydrophobic coatings, are not as lubricious as hydrophilic coatings and are therefore typically not able to be used in cases where a hydrophilic coating is needed.⁷³

ii. Industry Recognition of the Outsourced Hydrophilic Coatings Market

22. Defendants' own ordinary course documents recognize outsourced hydrophilic coatings as a distinct market, referring to the existence of a "hydrophilic coatings market," as well as an

⁶⁸ Stephens (J&J Shockwave) Dep. 97:16-98:9.

⁶⁹ Ankeny (Harland) 202:9-18, 203:20-204:4; *see also* Tieso (Fastwave) Dep. 36:8-12 ("I would consider it somewhat of a table stakes requirement to be competitive in the market.").

⁷⁰ Martin (Maduro) 683:8-10.

⁷¹ Eccles (Scientia) 466:7-11; 469:6-10.

[.] See also (He

⁷³ PFOF, *infra* ¶¶ 45-52.

PX1294 at 015 (Biocoat Positioning Workshop (Feb. 2025), labeling Harland and "Company M" (Surmodics) as Biocoat's "Primary Competitors" in "The hydrophilic coatings solutions marketplace").

"outsourced hydrophilic coatings market." Defendants view outsourced hydrophilic coatings as distinct from in-house hydrophilic coatings. 76

23. Other industry participants also recognize an outsourced hydrophilic coatings market.⁷⁷ Third-party hydrophilic coating suppliers list their competition as outsourced hydrophilic coating suppliers.⁷⁸ Likewise, third-party hydrophilic coating suppliers do not believe that they compete with "in-house coatings" as in-house coatings typically are not sold to third parties.⁷⁹

iii. Hydrophilic Coatings Are Supplied by Specialized Vendors

- 24. Customers in need of a hydrophilic coating seek out a supplier with a strong track record of success in the hydrophilic coatings business.⁸⁰ Customers repeatedly testified they look for a hydrophilic coating supplier that has the proper knowledge and expertise to optimize coatings to the customer's device.⁸¹ Hydrophilic coating suppliers leverage this expertise to win customers⁸² and to help customers get their devices to the market faster.⁸³
- 25. Medical device original equipment manufacturers ("OEMs") value the ability to partner with companies for which hydrophilic coatings are a core competency. As Mr. Eccles testified, "[w]e

⁷⁵ PX1118 at 011 ("Outsourced Hydrophilic Coatings Competitive Landscape");

76 PFOF, infra \$ 54.

77 See

78

Torti (Hydromer) Dep. 264:1-5 (listing "Big 3" as "Surmodics, Biocoat, and Harland" for hydrophilic coatings);

79

80

81 Eccles (Scientia) 471:21-472:10;

52 t'And so we chose to partner . . . when possible, with experts if it is not within our core competency.").

82 de Freitas (Biocoat) 531:16-532:16 (Biocoat's clinical experience record helps bring in new customers).

83 Gronda (Medtronic) 724:20-23 ("But if you work with, for example, engineers from Surmodics and Biocoat, they are able to get us to market faster because they know more about how to – how to troubleshoot and how to get the best coating.");

have spent a lot of time trying to become better, but the problem is that you really need the supplier's knowledge to work well. It's—coating is an art form. . . . So, having the supplier help you is key. So, that partnership is something I look for when I go to select a coating for a device."⁸⁴ It's about the painters, not just the paint for hydrophilic coatings.⁸⁵

- 26. Although some customers apply hydrophilic coatings themselves,⁸⁶ customers also value having experts at hydrophilic coating companies apply coatings, even where a customer may have a hydrophilic coating available in-house.⁸⁷
- 27. As Phil Ankeny, CFO of Harland, testified, "most medical device companies have a lot of really good mechanical engineers . . . but when it comes to things involving chemistry, they tend not to have as much core competency in that, and so outsourcing to a company like Harland can be really cost effective, and they don't have to invest in those people internally."⁸⁸
- 28. Mr. Ankeny further explained that this outsourcing helps customers because "It makes it very efficient because . . . time to market is very valuable. And so helping a customer get there as rapidly as possible is really what they're trying to do, particularly if they're a startup company and they only have limited funds. Doing it faster means they spend less."⁸⁹
- 29. Biocoat and Surmodics executives recognize the advantage of being a specialized hydrophilic coatings vendor, rather than a company that supplies both coatings and medical devices and therefore potentially competes with OEM customers.

⁸⁴ Eccles (Scientia) 471:21-472:10.

⁸⁵ Eccles (Scientia) 471:21-472:10.

⁸⁶ See, e.g., McCormack (Stryker) Dep. 52:24 - 53:06 (performs the application of the coating in-house).

⁸⁷

Jalgaonkar (Balt) Dep. 156:14-157:5 ("[W]e choose to partner with . . . experts if it is not within our core competency."); PFOF, *infra* ¶ 55.

⁸⁸ Ankeny (Harland) 209:16-210:14.

⁸⁹ Ankeny (Harland) 213:7-214:8.

⁹⁰ Then-Biocoat CEO Jim Moran recognized

this potential vulnerability of Surmodics, believing that Biocoat could potentially pick up new projects from Surmodics' customers due to Surmodics' entry into medical devices. 91

iv. Hydrophilic Coatings Pricing is Distinct

- 30. Hydrophilic coatings are significantly more expensive than other types of medical coatings. One customer testified that hydrophilic coatings typically cost approximately seven times as much as hydrophobic coatings. 92 Mr. Hutar of Piraeus explained that hydrophilic coatings are "the most expensive material, by far," of individual materials used to build Piraeus's medical devices. 93 Customers are willing to pay a significantly higher price for hydrophilic coatings because having a hydrophilic coating is important to the performance of their device. 94
- In contrast, UV-cured and thermal-cured hydrophilic coatings are priced similarly. 95 31.

v. Hydrophilic Coating Customers Are Sensitive to Price Changes

32. Customers often consider the pricing and pricing structure of a hydrophilic coating supplier before and after testing the coating for feasibility. 96 For example, Himanshu Patel, CEO of

; see Hutar (Piraeus) 404:4-10 (hydrophilic coating costs about \$100).

⁹¹ Moran (Biocoat) 785:23-786:1

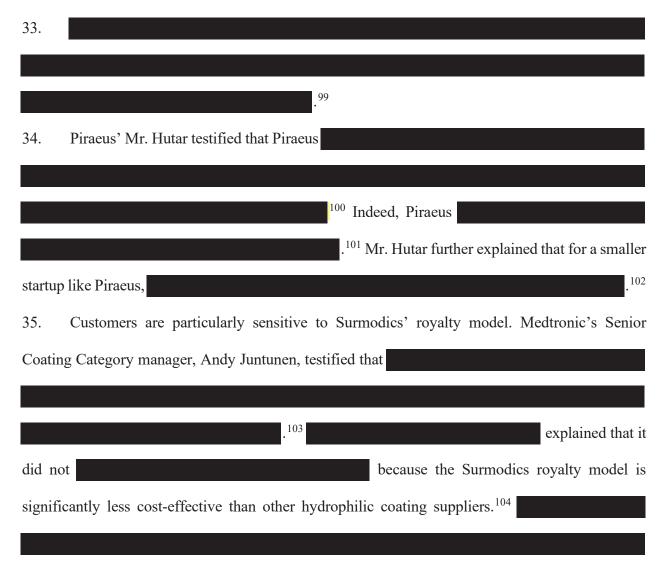
⁹³ Hutar (Piraeus) 404:4-10.

⁹⁴ Patel (Lumivascular) Dep. 101:19-102:2 ([W]e're willing to pay higher prices for higher performance.").

⁹⁵ de Freitas (Biocoat) 523:3-8 (discussing PX1228) ("O. And today, the price for a UV and thermal-cured sample kit is the same, correct? A. It is."); PX4000 (Fix Report) ¶ 104 ("pricing for UV-cured and thermal hydrophilic coatings are similar").

⁹⁶ Patel (Lumivascular) Dep. 102:22-103:6 (considered price before testing for feasibility); Eccles (Scientia) 481:9-19 ("Until Biocoat and ISurTec started coming along, we had never got Surmodics to ever consider not having a royalty . . . So that [pricing structure] plays a big part in looking at coatings, not only that, but having that competition."); Brenizer (Teleflex) Dep. 88:23-89:7 ("cost is always a factor"); Stern (Contego) 981:5-982:5 (considered pricing from Biocoat and Surmodics before selecting a coating supplier).

Lumivascular, stated that while performance is important, the company ultimately tries to keep the cost of every component "as low as possible." Mr. Hutar of Piraeus similarly testified that when choosing a hydrophilic coating supplier, Piraeus considers whether it believes the price of the coating service is going to continually increase or stay the same. 98



⁹⁷ Patel (Lumivascular) Dep. 101:19-109:2.

⁹⁸ Hutar (Piraeus) 404:17-405:5.

¹⁰⁰ 101 102 103 104

105

vi. Hydrophilic Coating Customers are Distinct

- 36. Customers for hydrophilic coatings are medical device companies and OEMs that manufacture devices that require a high level of lubricity. 106
- 37. In fiscal years 2022 and 2023, neurovascular, peripheral vascular, coronary vascular, and structural heart accounted for of Surmodics' total royalty revenue. Neurovascular applications were responsible for of Surmodics' royalties and are
- 38. Likewise, for Biocoat, neurovascular devices are the largest market segment by revenue, and cardiovascular devices are the third largest market segment by revenue. 109

vii. The Relevant Product Market Includes Both UV-cured and Thermalcured Hydrophilic Coatings

39. Both UV-cured and thermal-cured hydrophilic coatings can be used for the majority of hydrophilic coating applications. ¹¹⁰ The curing method is immaterial to the coating's ultimate purpose: providing lubricity to facilitate movement through the body's vasculature. ¹¹¹ Customers

Dang (Terumo Neuro) Dep.

108

Petra (DSM) 304:22-25; Maharaj (Surmodics) 1013:11-14; PFOF, *supra* ¶¶ 18-20 (discussing why hydrophilic coatings are favored for neurovascular, peripheral vascular, and cardiovascular applications).

Hance (Biocoat) 1362:6-24. Ophthalmic devices make up a slightly larger percentage of revenue than cardiovascular devices for Biocoat.

Gronda (Medtronic) 728:24-729:2 (both thermal and UV are options for a majority of medical device substrates); Hergenrother (Biocoat) 1471:2-8 (both work pretty well on same materials);

[;] Epps (Terumo Medical) Dep. 53:19-54:2; Jalgaonkar (Balt) Dep. 152:22-153:4; Borgaonkar (Heraeus) Dep. 39:21-25, 42:2-4, 45:18-21, 46:10-14; Patel (Integer) Dep. 114:7-115:13 (admitting "there's no doubt in my mind [UV and thermal] are interchangeable" because "both offer the same properties").

^{34:2-4, 34:7-11 (}both provide "lubricity in the fluid environment").

select the hydrophilic coating with the best performance and price, regardless of curing method. ¹¹² *No* third party testified that a coating failed feasibility testing due to curing method.

- 40. Customers repeatedly testified that UV-cured and thermal-cured hydrophilic coatings are close substitutes that serve the same purpose and compete head-to-head with each other. The only other significant competitors in the market—DSM and Harland—also testified that UV- and thermal-cured hydrophilic coatings are close substitutes and compete head-to-head.
- 41. Defendants testified—and their ordinary course documents make clear—that UV-cured and thermal-cured hydrophilic coatings are close substitutes that serve the same purpose, can be used on the same medical devices and substrates, and compete for customers. Surmodics' marketing materials compare its latest-generation UV-cured coating, Preside, against Biocoat's thermal-cured coating. Almost everyone on Biocoat's R&D and Application Development Teams works on both

(discussing PX6090). See also

; PX2300 at 003 (Surmodics press release comparing Preside to thermal-cured

and UV manuals identifying substrates compatible with both UV-cured and thermal-cured coatings).

hydrophilic coatings) (Oct. 31, 2023).

[:] Hutar (Piraeus) 403:15-404:3 (performance is the "number one" criteria used to evaluate suppliers); de Freitas (Biocoat) 519:9-12; Tompkins (Penumbra) Dep. 72:16-22 ("Penumbra selects the coatings based on performance."). ¹¹³ See McCormack (Stryker) Dep. 55:5-8 (Stryker considers both curing methods when developing new medical devices); Stern (Contego) 976:25-977:14 (either Biocoat thermal or Surmodics UV's performance "would be acceptable"); Eccles (Scientia Vascular) 478:10-14; Patel (Lumivascular) Dep. 133:1-9; Patrick (Midwest) Dep. 106:7-18, 107:8-24, 108:2, 109:1-5); ¹¹⁴ See see also Lydon (Argon) Dep. 51:9-52:2 ("[I]f a company is looking for a hydrophilic coating, they're going to explore all options."). ¹¹⁵ See de Freitas (Biocoat) 519:19-520:7; Hance (Biocoat) 1367:14-19; see also PX1228 at 013 (internal Biocoat email) ("[I]n terms of performance, you can expect no significant difference between [Biocoat's] UV and Thermal coatings."); PX1277 at 001 (de Freitas (Biocoat) responding to a customer email: "Yes, we can coat both metal and polymers with our coatings (both UV and Thermal)."); id. (telling customer, "Our UV and Thermal have similar results"); ; PX1313 at 42-43, 71 (Biocoat's thermal

UV- and thermal-cured coatings. 117 And the record is replete with examples of customers who tested Defendants' UV-cured and thermal-cured coatings head-to-head on the same devices. 118

- 42. UV-cured and thermal-cured coatings compete against each other even though they are applied using different equipment. When developing a new device, customers first choose a coating, then buy the corresponding equipment. UV-cured with multiple devices sometimes have the equipment necessary to apply both UV-cured and thermally-cured coatings. Even when customers already have equipment used with one curing method but not the other, they still consider coatings with both curing methods. Finally, many customers never purchase coating equipment, and instead outsource coating application to either a third party or the coating supplier itself.
- 43. Inner diameters represent a ."123

 Moreover, there are circumstances and methods allowing either UV-cured or thermal-cured hydrophilic coatings to be used on the inner diameter of a medical device. 124
- 44. Although UV-cured coatings typically cure faster than thermal-cured coatings, the total application time for a UV-cured coating is not always faster than for a thermal-cured coating, since total application time ultimately depends on the device and its coating-specific application

¹¹⁷ Hergenrother (Biocoat) 1458:17-21; 1459:2-4; Hance (Biocoat) 1358:1-2.

118 See, e.g.,

(describing multiple examples of UV and thermal competition);

120 Cf.

121 Eccles (Scientia Vascular) 471:1-5;

Stephens (J&J Shockwave) Dep. 28:11-16;

, 91:25-92:15;

122 Hergenrother (Biocoat) 1468:14-23;

(Surmodics) 346:18-24.

123

124

process. ¹²⁵ Customers generally did not cite curing time as one of the most important factors they consider when choosing a hydrophilic coating supplier. ¹²⁶

viii. Hydrophobic Coatings are Not Reasonably Interchangeable with Hydrophilic Coatings

- 45. Hydrophobic coatings work differently than hydrophilic coatings: whereas hydrophilic coatings are water loving and reduce friction by absorbing water, hydrophobic coatings reduce friction by repelling water. Hydrophobic coatings provide some lubricity but are "a couple of orders of magnitude less lubricious than a hydrophilic coating." Due to their inferior lubricity, hydrophobic coatings like PTFE are not typically considered alternatives to hydrophilic coatings for the outer diameter of interventional devices such as catheters. 129
- 46. There are various types of hydrophobic coatings, such as PTFE, silicone oils, and parylene. Each of these materials produces higher friction than hydrophilic coatings. ¹³⁰
- 47. Hydrophilic coating customers and suppliers agree that hydrophobic coatings are not an

[;] Hergenrother (Biocoat) 1466:21-1467:4; *see*, *e.g.*, PX1390 at 001-02 (recommending Biocoat's thermally-cured coating over Biocoat's UV-cured coating, because although "performance between the two curing systems will be the same," production rates for the thermally-cured coating would be greater); *cf.* Hiatt (Cook Medical) Dep. 50:16-51:5 (thermally curing multiple devices at once can "offset" the difference in cure time).

¹²⁶ See, e.g., 403:15-404:3 (considering cost, then ease of service);

[;] Hutar (Piraeus)

[;] Stern (Contego) 974:7-20 (considering biocompatibility and history of FDA clearances); Dang (Terumo Neuro) Dep. 38:1-5, 38:7-14, 38:16-39:1 (considering reputation and supply continuity);

Rentschler (Aspero) Dep.

^{39:7-40:13 (}considering biocompatibility and cost); Patel (Lumivascular) Dep. 109:16-18, 109:22-110:10 (considering stability, price, and coating services).

¹²⁷ Stern (Contego) 973:5-10.

¹²⁸ Ankeny (Harland) 228:21-24.

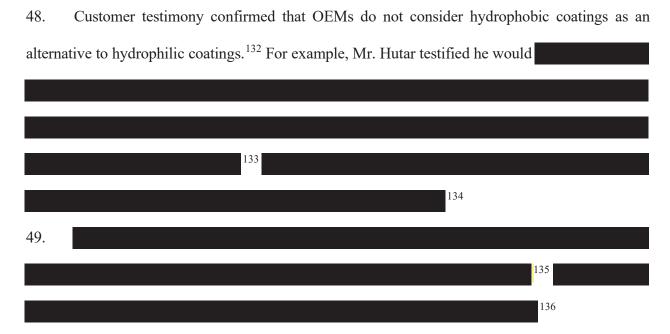
Gronda (Medtronic) 729:8-17; Stephens (J&J Shockwave) Dep. 103:12-104:16 ("In my experience [hydrophobic coatings are] not as lubricious as the hydrophilic coatings.");

¹³⁰ Hergenrother (Biocoat) 1460:16-1461:3 (PTFE, or Teflon); Hergenrother (Biocoat) 1419:6-11; 1461:17-

^{24 (}parylene); Patel (Lumivascular) Dep. 98:1-98:13 (parylene);

[;] Stephens (J&J Shockwave) Dep. 105:3-106:6 (silicone oil); see

alternative to hydrophilic coatings. Mr. Ankeny of Harland testified that in his experience, hydrophobic and hydrophilic coatings are "not substitutes for one another." ¹³¹



50. Even for those medical device applications where the lubricity of PTFE is sufficient, there has been a movement away from PTFE because of "safety issues with fluorochemicals, . . . the building blocks that are used to make PTFE." Customers would therefore be unlikely to switch

Stephens (J&J Shockwave) Dep. 103:12-104:16 ("it's unlikely we would evaluate hydrophobic coatings for the Shockwave catheters... Because we're trying to optimize lubricity, and lubricity is more easily achieved with a hydrophilic coating, not a hydrophobic coating."); Moll (Becton Dickinson) Dep. 78:16-20 ("Q. [A]re you aware of any instance where BD has switched from a hydrophilic coating to a hydrophobic coating for the same use? A. No.");

Ankeny (Harland) 230:6-19; *see* Lydon (Argon) Dep. 44:7-16 (Q. Would you consider hydrophobic coatings to be a direct substitute for hydrophilic coating? A. No, I would not. Q. Why not? A. Just based on the reduction in coefficient of friction. It's not as great with the hydrophobic coatings.").

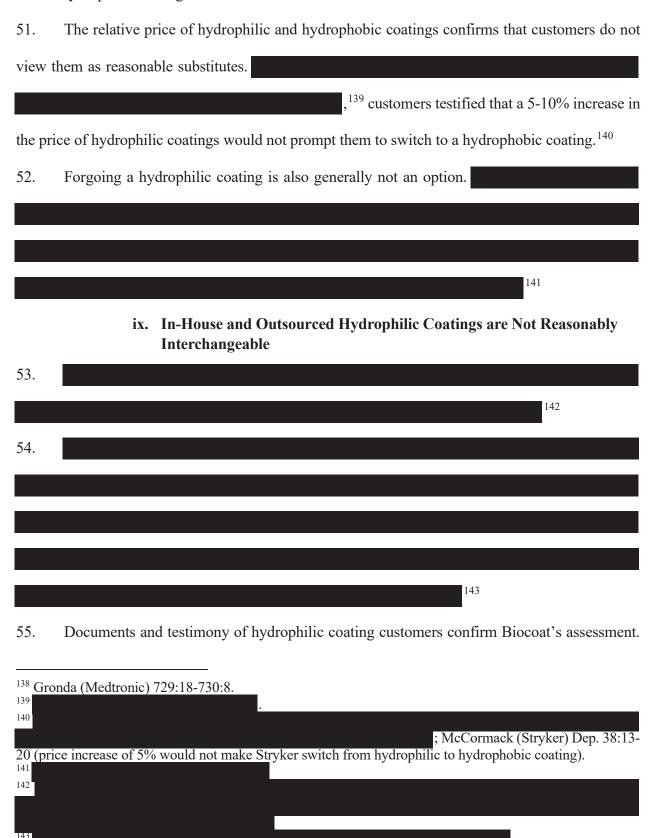
132 Eccles (Scientia) 470:11-14;

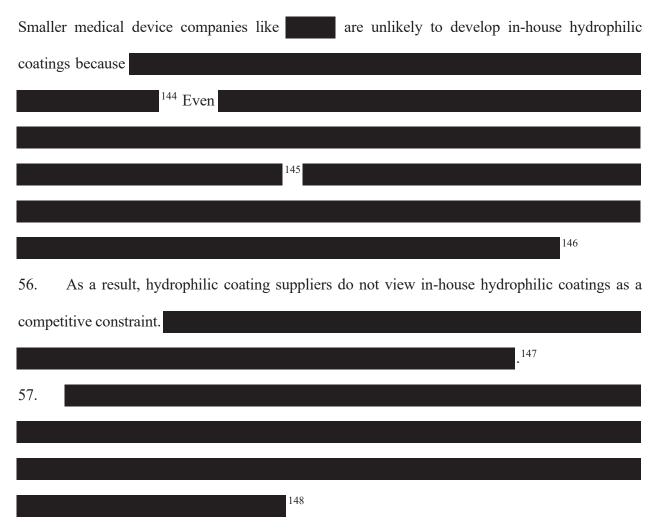
Patel (Lumivascular) Dep. 98:1-98:13.

Patel (Lumivascular) Dep. 98:1-98:13.

Gronda (Medtronic) 729:18-730:8.

from a hydrophilic coating to PTFE. 138





Plaintiffs' expert Dr. Aaron Fix confirmed that, for "customers currently using outsourced coatings," in-house hydrophilic coatings are "by definition not an option" because "[y]ou can't buy one on the open market, and you can't develop one in the next couple of years for sure." Because some medical device manufacturers have their own hydrophilic coating but still buy from Biocoat and Surmodics, Dr. Fix would not "expect much substitution towards the in-source coating because,



again, they're using the outsourced coating at a greater expense because they have a need for it."149

b. Outsourced Hydrophilic Coatings Satisfies the Hypothetical Monopolist Test

- 59. The hypothetical monopolist test, or HMT, "is a generally accepted economic test for whether a group of products constitutes a relevant antitrust market." Experts agree that it is one method, along with the practical indicia, for defining a relevant antitrust product market. 151
- 60. The HMT "is used the quantify the degree of sufficient (or insufficient) substitution and test the boundaries of the relevant market" by asking whether it would be profitable for "a hypothetical monopolist of a candidate relevant market" to raise "the price of goods in that market by a small but significant amount ('SSNIP')." "If substitution by customers out of that candidate market . . . would render that hypothetical price increase unprofitable, then the candidate product market is too small, and the process is repeated with a larger market" ¹⁵³
- 61. The HMT here asks whether a hypothetical monopolist owning all sources of outsourced hydrophilic coatings could profitably raise the price of one coating product, or whether customers would substitute to something outside of the market, like a hydrophobic coating, or no coating at all, such that the price increase would be unprofitable.¹⁵⁴
- 62. The candidate market—outsourced hydrophilic coatings for U.S. medical devices—satisfies the hypothetical monopolist test. 155 And by a wide margin: the test would be satisfied even "if incremental margins were half" the level calculated for Biocoat and Surmodics "and the aggregate diversion ratio was assumed to be half of its likely true value[.]" 156

¹⁴⁹ Fix 1094:2-1095:16.

¹⁵⁰ PX4000 (Fix Report) ¶ 17; see also DX736 (Wong Report) ¶ 238.

¹⁵¹ DX736 (Wong Report) ¶ 238; PX4000 (Fix Report) ¶ 58.

¹⁵² DX736 (Wong Report) ¶ 238; PX4000 (Fix Report) ¶ 92.

¹⁵³ DX736 (Wong Report) ¶ 238; see also Fix 1099:19-1100:9.

¹⁵⁴ Fix 1099:19-1100:24.

¹⁵⁵ PX4000 (Fix Report) ¶¶ 96-98, Table 2.

¹⁵⁶ PX4000 (Fix Report) ¶ 99; Fix 1103:2-9.

63. Defendants' economist Dr. Paul Wong alleges that "many candidate markets" could satisfy the hypothetical monopolist test ¹⁵⁷ but does not contend that the market for outsourced hydrophilic coatings fails the hypothetical monopolist test. ¹⁵⁸

159

VI. THE RELEVANT GEOGRAPHIC MARKET IS THE UNITED STATES

- 64. The relevant geographic market is the United States. The U.S. Food and Drug Administration ("FDA") has stringent regulatory requirements for selling medical devices in the United States, including testing to meet regulatory standards and gain FDA approval. ¹⁶⁰
- 65. Medical devices that commonly require hydrophilic coatings, such as neurovascular, cardiovascular, and peripheral vascular interventional devices, typically require FDA approval prior to being marketed and sold in the United States.¹⁶¹

. 162 Thus, medical device companies seek out coating providers that have previously received FDA approval. 163

66. Medical device companies seeking FDA approval value hydrophilic coating suppliers located in the United States, as the services are logistically closer to production of the devices. 164

VII. MARKET STRUCTURE AND CONCENTRATION

a. Biocoat and Surmodics are the Two Largest Hydrophilic Coating Suppliers



¹⁵⁷ DX736 (Wong Report) ¶ 30.

¹⁶⁰ Juntunen (Medtronic) 78:9-21.

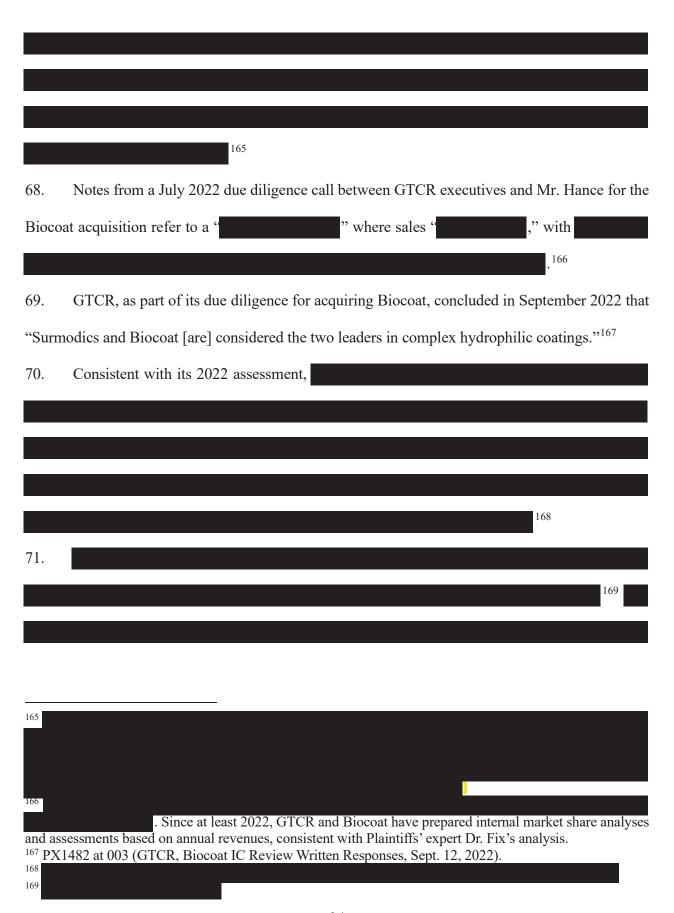
¹⁵⁹

de Freitas (Biocoat) 518:4-7 (referring to PX1272 at 003).

¹⁶²

¹⁶³ de Freitas (Biocoat) 518:18-20.

¹⁶⁴ Hance (Biocoat) 1321:3-20 ("Surmodics exclusively does some services on a limited basis in the Minneapolis area, but we have at Biocoat, and I suspect there are Surmodics customers too, have -- would like to see services closer to production."). See PFOF, infra ¶ 92.

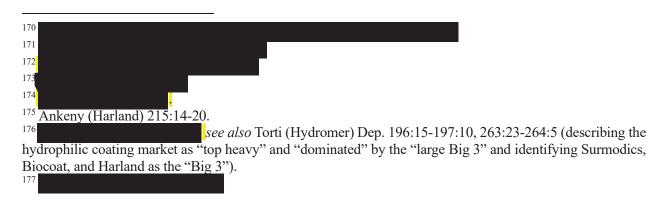


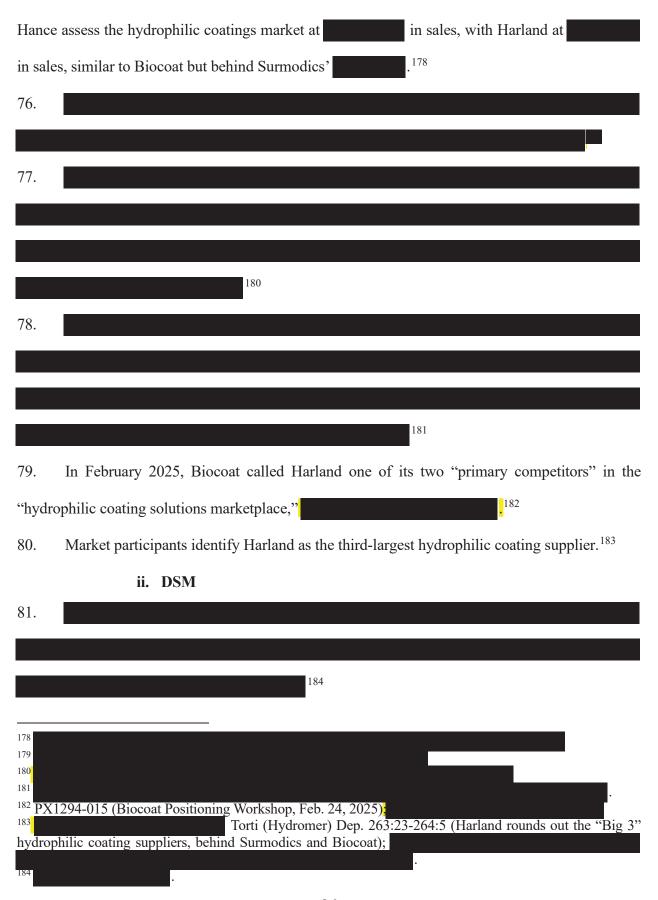


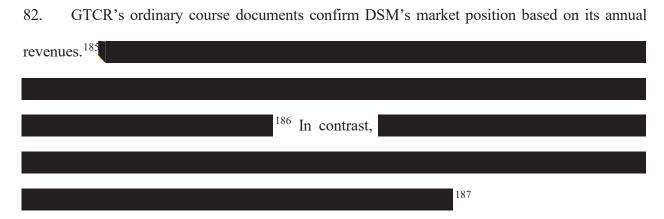
b. Other Suppliers Have Substantially Smaller Market Shares

i. Harland

75. In its due diligence for the Biocoat acquisition, GTCR's notes from a July 2022 call with Mr.



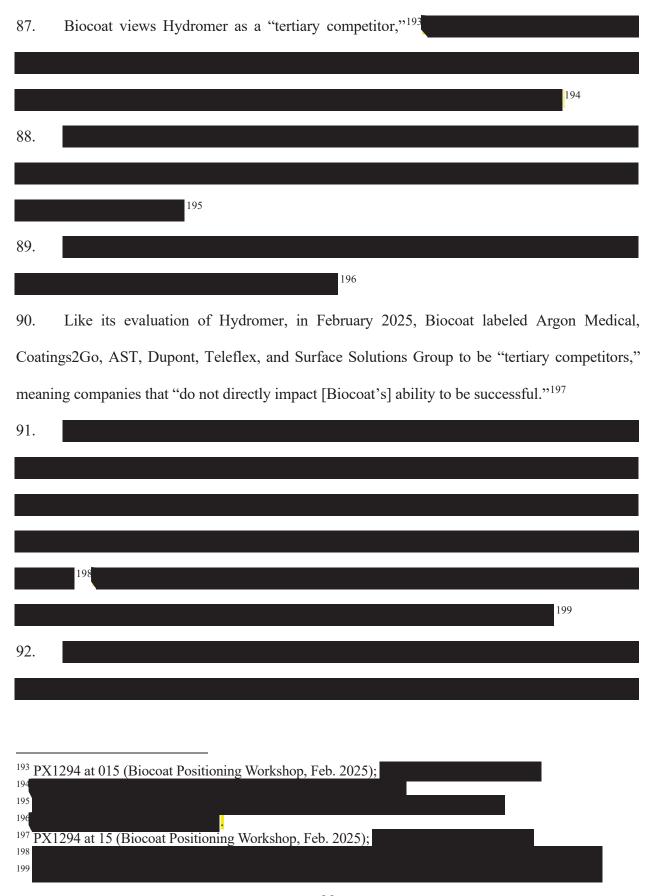




- 83. Recent internal Biocoat documents reflect the same view. A 2025 positioning workshop presentation prepared using feedback from senior Biocoat executives, describes DSM as a "tertiary competitor," meaning it "do[es] not directly impact [Biocoat's] ability to be successful." 188
 - c. Remaining Hydrophilic Coating Suppliers Have Substantially Smaller Presences and Lack Key Capabilities
- 84.
- 85. Particularly for large medical device companies, many hydrophilic coating providers are too small and do not have the resources or ability to support a large customer. 190
- 86. Hydromer assesses its share of the relevant market as roughly one percent. Hydromer's CEO described the company's financial situation as "precarious," its credit rating as "horrendous," and stated that Hydromer has not been successful in attempts to secure additional financing. Hydromer accordingly has no expansion plans. 192

¹⁸⁵ PX1108 at 004 (GTCR, Biocoat – Coatings Catch Up with Chip Call Notes, July 27, 2022);

186
187
188 PX1294-015 (Biocoat Positioning Workshop, Feb. 24, 2025);
189
190 PX3110-004; see Juntunen (Medtronic) 113:15-24.
191 Torti (Hydromer) Dep. 34:6-35:11.
192 Torti (Hydromer) Dep. 224:8-227:19.





93. Margaret Lydon of Argon testified that Argon is "no longer actively researching or developing" hydrophilic coatings and no longer "actively search[es] out new customers." ²⁰¹

94.

202

95. Contego initially used a hydrophilic coating from TUA Systems and faced significant delays in developing and commercializing its aspiration catheter when TUA's coating failed FDA testing. Afterwards, Contego only reached out to coating suppliers that had previously coated a commercialized product because these suppliers presented less risk. 204

VIII. THE PROPOSED ACQUISITION WILL SUBSTANTIALLY LESSEN COMPETITION

- a. The Proposed Acquisition Results in Presumptively Illegal Market Shares and Concentration Levels
- 96. A merger is presumptively unlawful if (a) it would result in a change in the Herfindahl-Hirschman Index ("HHI") greater than 100, and (b) either the post-merger HHI would exceed 1,800, or the merger would result in a market share for the combined firm greater than 30%. ²⁰⁵
- 97. Based on 2024 total revenue, Surmodics has a share of the relevant market and Biocoat has a share, making Defendants' combined market share .206 "The estimated market shares imply a pre-merger HHI of 2,483, a post-merger HHI of 3,998, and a change in HHI

²⁰¹ Lydon (Argon) Dep. 23:21-24:22.

²⁰³ Stern (Contego) 970:17-972:7; 973:11-975:8.

²⁰⁴ Stern (Contego) 972:3-975:8.

²⁰⁵ See PCOL, infra ¶ 291.

²⁰⁶ PX4000 (Fix Report) ¶ 113, Figure 5.

of 1,515. All concentration measures significantly exceed the threshold for structural presumption cited in the Merger Guidelines" and embraced by courts.²⁰⁷ These total revenue figures, based on data produced in this litigation pursuant to subpoenas, are more accurate than comparable information and estimates used in the ordinary course of business.²⁰⁸

- 98. Alternative calculations focused on new customers and opportunities are in accord. Dr. Fix calculated market shares based on revenue from new customers in 2023 and found that Surmodics' share was and Biocoat's share was 209 Suppliers' shares based on 2024 pre-commercial development revenue give Surmodics a share and Biocoat a share.²¹⁰
- 99. When accounting for Integer's hypothetical presence in the market post-divestiture, the proposed acquisition is still presumptively unlawful. The merged firm would have over market share, and the change in HHI is well in excess of the threshold for presumptive illegality.²¹¹
- 100. Using the FDA data favored by Dr. Wong, the market share for devices known to have a hydrophilic coating still yields market shares and changes in concentration exceeding the thresholds for a presumption of illegality, even when accounting for Integer in the market.²¹²

i. Revenue Is a Reliable Measure of Market Shares in This Industry

- 101. Annual revenues are a standard metric by which to assess market shares and market concentration and is an approach consistent with the recommendations of the Merger Guidelines and taken by courts across the country in merger cases.²¹³
- 102. The use of revenue to calculate market share is also consistent with how industry participants

 $^{^{207}}$ PX4000 (Fix Report) ¶ 114, Table 3 (internal citations omitted); Fix 1107:22-1108:6; PCOL, *infra* ¶ 291. 208 Fix 1108:7-18.

²⁰⁹ PX4000 (Fix Report) ¶ 128, Figure 7; PX4013 (Fix Rebuttal) ¶¶ 106-109.

²¹⁰ PX4000 (Fix Report) ¶ 129, Figure 8; PX4013 (Fix Rebuttal) ¶¶ 110-113.

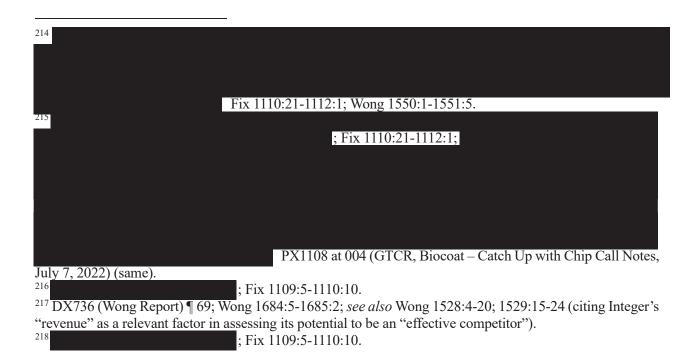
²¹¹ PX4013 (Fix Rebuttal) ¶¶ 220-221, Figure 7; Fix 1154:17-1155:10.

²¹² PX4013 (Fix Rebuttal) ¶¶ 129, 149, Table 2; Fix 1129:16-1131:23; 1908:8-21.

²¹³ PX4000 (Fix Report) ¶ 120; PX4013 (Fix Rebuttal) ¶¶ 97-103, 108. *See* PCOL, *infra* ¶¶ 294-97.

track market shares in the real world. Witness testimony and documents demonstrate that hydrophilic coating market participants typically track market share and the relative size of hydrophilic coating companies based on revenue.²¹⁴ Defendants similarly rely on revenue-based analysis to determine current market share and competitor size.²¹⁵

- 103. Revenue is particularly relevant in assessing competitive significance in the hydrophilic coating industry because it reflects supplier capabilities, including research and development competence, production capacity and quality, and FDA track record.²¹⁶ Dr. Wong concedes that revenue streams from legacy coatings and customers are relevant to "ongoing competition" and contribute directly to "future innovation."²¹⁷ Information about revenues is also relevant to assessing competitive significance because it captures established customer relationships, which are often dispositive in a market like this one where there is a strong incumbency advantage.²¹⁸
- 104. Revenue-based market share calculations are consistent with the evidence in this case, in particular the overwhelming evidence demonstrating that Surmodics and Biocoat are the #1 and #2



options for many hydrophilic coatings customers.²¹⁹ Revenue-based market share calculations also accurately reflect party and third-party assessments of market size²²⁰ and other calculations.²²¹ Defendants and other market participants rely on this revenue-based analysis to make decisions about the current market and plan for the future.²²²

ii. Market Share Calculations Based on FDA Data, When Performed Correctly, are in Accord

105. Eschewing the use of the revenue data widely used in similar antitrust cases and in this industry by market participants, Dr. Wong instead purports to calculate market share using FDA data which, he argues, is the only data unbiased by "legacy revenue."²²³ This data, based on forms that device makers file with the FDA,²²⁴ requires Dr. Wong to make "assumptions about which devices are likely to have a hydrophilic coating and how many of them,"²²⁵ and do not provide information about the supplier who provided the coating, should one be present.²²⁶

106. Dr. Wong's calculations are based on a universe of "coating eligible" devices, which Dr. Wong generated using 151 FDA product codes he believed to be associated with hydrophilic-coated devices. ²²⁷ Over half of these product codes do not feature a single approved device over the past 11

²¹⁹ PX4000 (Fix Report) ¶ 125 (collecting evidence); see also PFOF, supra ¶ 67-74.

²²⁰ See generally Fix 1110:21-1112:7; PX4000 (Fix Report) ¶¶ 118-119, Figure 6; Wong 1623:12-1624:21;

Fix 1119:13-1121:1 (shares based on new customer revenues and pre-commercialization revenues); PX4000 (Fix Report) ¶¶ 127-130, Figures 7, 8; PX4013 (Fix Rebuttal) ¶¶ 147-153, Table 2.

²²² See, e.g.,

²²³ Wong 1526:20-1527:3.

²²⁴ Fix 1126:12-1127:3.

²²⁵ Fix 1890:24-1891:12.

²²⁶ PX4013 (Fix Rebuttal) ¶ 124; Wong 1551:17-1553:16 ("almost all of these devices use − some form of lubricity. They don't always use hydrophilic coatings . . . the public data doesn't identify, one by one, the specific lubricious coating option chosen.").

²²⁷ Fix 1891:24-1893:14; Wong 1597:1-22.

years that can be confirmed to use a hydrophilic coating. ²²⁸

107. These codes produced a data set of 213 devices in 2024, including 45 that use a hydrophobic coating or are uncoated.²²⁹ Of the remaining devices, 91 were confirmed to have hydrophilic coatings based on information in the FDA filings or the parties' data.²³⁰ Of the 77 devices lacking any information about the presence or absence of a hydrophilic coating, Dr. Wong assumed that 51.52 devices would have hydrophilic coatings, based only on product codes, not any independent, device-by-device verification.²³¹

108. Dr. Wong admitted that one reason an FDA form might not identify a hydrophilic coating is because a device does not, in fact, use a hydrophilic coating,²³² which is particularly likely given FDA guidance directs device makers to describe the presence of a hydrophilic coating on their labels and in their 510(k) submissions.²³³

109. Dr. Fix and his team reviewed the 77 devices without coating information and found numerous examples of devices, such as computer cables and software, that would never have hydrophilic coatings.²³⁴ Dr. Wong did not dispute the presence of these devices in his market share denominators.²³⁵ Dr. Fix estimated that 2 of the 77 devices actually have hydrophilic coatings—far below the 51.52 assumed by Dr. Wong.²³⁶ Yet, Dr. Wong relied on this assumption, along with the 91 confirmed coated devices, to calculate post-merger market shares of just 22% for the merged

²²⁸ Fix 1891:24-1893:14.

[;] Fix 1894:15-1896:24.

²³⁰ Wong 1601:8-1602:25.

²³¹ Wong 1603:1-1606:1.

²³² Wong 1606:2-5.

²³³ Fix 1897:25-1899:7 ("[I]f the disclosure to the FDA doesn't mention the hydrophilic coating, the most likely assumption is that there's no hydrophilic coating on the device."); Fix 1900:6-25.

²³⁴ Fix 1126:13-23, 1902:7-1904:6; PX4013 (Fix Rebuttal) ¶¶ 135, 138; Wong 1562:13-1563:1, 1607:21-1615:7.

²³⁵ Wong 1562:13-1563:1; Wong 1607:21-1615:7.

²³⁶ Fix 1915:4-12.

firm.²³⁷ Dr. Wong cannot say who coated any of the 51.52 devices, nor can he say which particular competitors make up the 78% market share he does not attribute to Biocoat and Surmodics.²³⁸

110. Dr. Fix testified that market shares based only on the 91 devices known to have hydrophilic coatings would be an "unbiased sample," but Dr. Wong did not perform this analysis. Dr. Fix did, and found that 35% to 44% of the 91 devices were coated by Biocoat and Surmodics, even when the devices were not weighted for revenue or size of opportunity. This calculation results in a post-merger concentration and change in concentration that is presumptively unlawful and is consistent with the calculations based on total revenues. These presumption thresholds were surpassed even when Dr. Fix attributed devices coated by Biocoat's UV-cured coating to Integer.

b. The Proposed Acquisition Would Eliminate Head-to-Head Competition

111. Competition for medical devices occurs at nearly every stage of engagement between a hydrophilic coating supplier and a medical device company, starting at the pre-feasibility stage.²⁴⁴ Mr. McCormack of Stryker testified that Biocoat and Surmodics compete pre-feasibility by marketing themselves at trade shows and forums.²⁴⁵ Biocoat head of sales Josh de Freitas testified that Biocoat competes with other suppliers pre-feasibility on reputation (clinical and financial), prior FDA success, by attending trade shows, and through outreach to potential customers.²⁴⁶

i. Customers View Biocoat and Surmodics as Direct Competitors

²³⁷ Fix 1128:2-10.

²³⁸ Fix 1128:11-1129:4; Wong 1627:18-1629:9.

²³⁹ Fix 1904:12-25.

²⁴⁰ Wong 1566:25-1567:14.

²⁴¹ Fix 1129:16-1131:12.

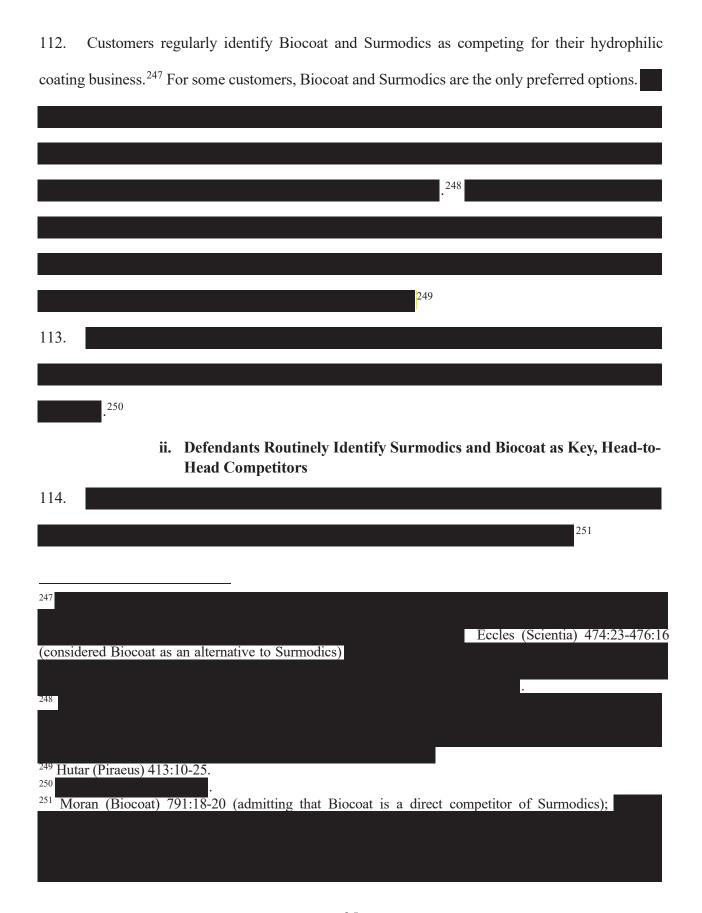
²⁴² Fix 1130:15-1131:23; see PCOL, infra ¶¶ 293-98.

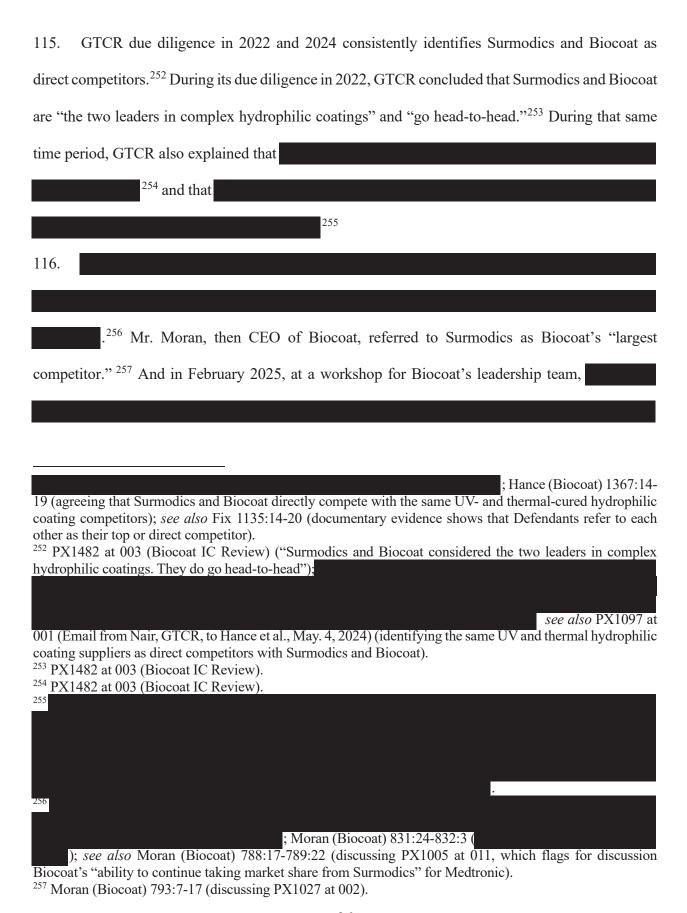
²⁴³ Fix 1905:8-1908:21.

²⁴⁴ de Freitas (Biocoat) 532:13-24; 539:19-22 (Biocoat competes for customers at the pre-feasibility stage);

²⁴⁵ McCormack (Stryker) Dep. 45.21-46.14.

²⁴⁶ de Freitas (Biocoat) 532:13-21; 533:3-15.





117. Likewise, Surmodics' most senior executives, including CEO Gary Maharaj, and the President of Surmodics' medical coatings business, Charlie Olson, repeatedly identify Biocoat as a or "top" competitor in recent, ordinary course communications. ²⁵⁹ In November 2022, when GTCR invested in Biocoat, Mr. Olson texted Mr. Maharaj, "the coatings war is on!!!" to which Mr.

Maharaj responded with a boxing glove emoji (). 260

This coatings war is reflected in head-to-head competition. In February 2024, Mr. Olson wrote of "we have another unique opportunity to flip competitive business from Biocoat."²⁶¹
That same month, Mr. Moran wrote, "we are 'hunting for conversion' of Surmodics coatings[.]"²⁶²
119. Likewise, Surmodics' Mr. Ventura described numerous head-to-head competitive opportunities against Biocoat.²⁶³ When asked to provide a list of "known or suspected devices using known competitor coatings," Mr. Ventura identified ten opportunities; for six of those opportunities,

²⁵⁸ PX1294 at 015 (Biocoat Positioning Workshop, Feb. 24, 2025);

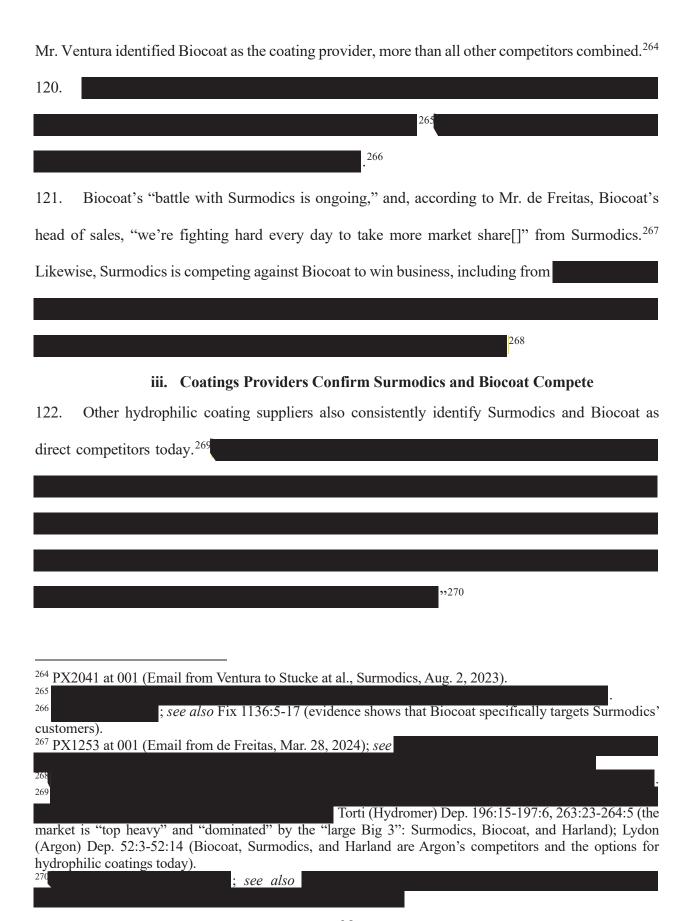
²⁵⁹ See PX2051 at 001 (Email from Olson, Surmodics, to J. Stender, J.M. Stender, Sept. 19, 2023) (identifying Biocoat as a "top competitor[]"); PX2048 at 001 (Surmodics email from Olson to Manders, July 25, 2022) (identifying Surmodics' coatings competitors as "1) Biocoat" and "2) Harland"); see also

²⁶⁰ PX2006 at 002.

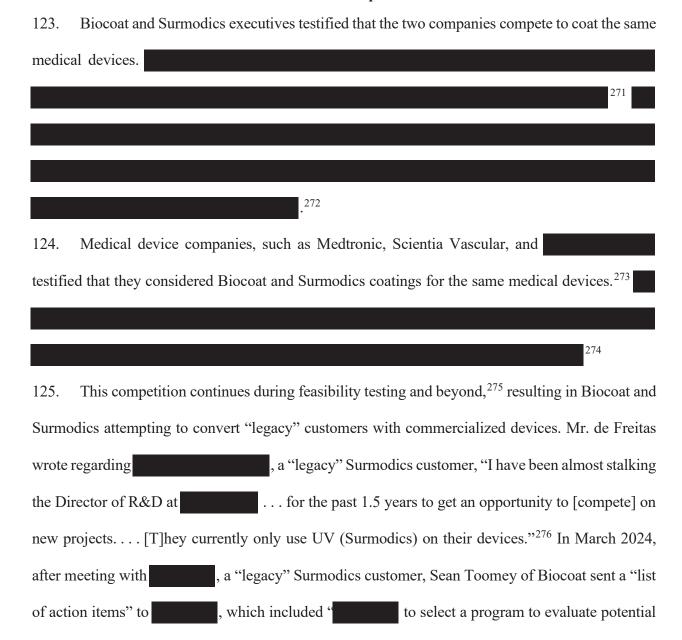
²⁶¹ PX2057 at 001 (Email from Olson to Carlson, et.al., Surmodics, Feb. 29, 2024)

²⁶² PX1060 at 002; Moran (Biocoat) 797:6-9.

²⁶³ See PX2098 at 001 (Email from Ventura to Xiong, Surmodics, July 25, 2024) ("We'll need the most competitive coating we have to compete against Biocoat."); PX2075 at 001 (Surmodics email from Ventura to Millitello) ("[T]he onus will be on our team to provide coated samples that are comparable, if not better. If we are unable to, we will lose a major to Biocoat."); PX2079 at 02 (Text message from Ventura to Olson, Surmodics, June 12, 2024) ("Using their production recipe, Biocoat chemistry scored consistent as a 4 out of 5.... The process changes [Surmodics] evaluated onsite improved [Surmodics'] coating results from a 2 to a 3.5-4 score."); PX2061 at 001 (Email from Ventura to Peterson, Surmodics, Apr. 4, 2023) ("For the coating we [Surmodics] are competing against the most is Biocoat along with Harland/Isurtec coating"); PX2065 at 001 (Email from Ventura to Xiong, Surmodics, June 13, 2023) ("International Comparing our coating head to head against Biocoat and possibly Harland.").

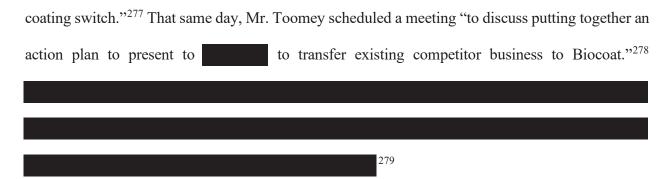


iv. Biocoat and Surmodics Compete to Coat the Same Medical Devices



²⁷¹ 272 273 Eccles (Scientia) 479:11-16; 274 275

²⁷⁶ PX1438 at 001 (Biocoat email from de Freitas to Moran, Apr. 21, 2022); de Freitas (Biocoat) 540:16-25; 542:1-5 (discussing PX1438).



c. Competition Between Biocoat and Surmodics Has Led to Decreased Pricing and Increased Innovation

i. Biocoat and Surmodics Compete on Price

126. Biocoat and Surmodics have competed vigorously on price for years and continue to compete today; Dr. Fix's merger simulation indicates that the loss of this competitive constraint due to the merger would incentivize Biocoat to raise prices by about 28% and Surmodics by about 13%. 280 127. Mr. Moran and Mr. de Freitas of Biocoat both testified that Biocoat has adjusted its pricing structure in attempts to win business from Surmodics. In July 2022, believing that Surmodics was "feeling the pinch of the market from Biocoat," 281 Mr. Moran directed Biocoat Vice President of Business Development Joe Sandora "to reduce per-piece pricing" to potentially "lock up more volume." 282 In January 2024, recognizing that "Scientia is currently utilizing Surmodics," Mr. de Freitas recommended to Mr. Sandora to "present a materials-only pricing option, excluding royalties, as the most compelling strategy" in an attempt to "establish a competitive edge over Surmodics... and win this competitive market share opportunity." 283

²⁷⁷ PX1553 at 004 (Biocoat email to re: Biocoat Lunch w/Attach: "Biocoat Overview – 03-14-24.pdf"); Toomey (Biocoat) Dep. 192:16-20, July 11, 2024).

²⁷⁸ PX1695 at 001 (Biocoat email re: Competitive Takeaway Proposal, Mar. 14, 2024).

²⁸⁰ Fix 1143:8-15.

²⁸¹ Moran (Biocoat) 784:17-24 (discussing PX1021 at 001 (Biocoat email re Surmodics Earnings Call)).

²⁸² Moran (Biocoat) 786:14-787:3 (discussing PX1021 at 001 (Biocoat email re Surmodics Earnings Call)).

²⁸³ PX1437 at 001-02 (Biocoat email re "Strategic Pricing Proposal for Scientia Vascular Collaboration").



130. Senior Biocoat and Surmodics executives testified that the two companies compete on services and customer support. Mr. de Freitas testified that Biocoat competes with other hydrophilic coating suppliers on reputation (clinical and financial), prior FDA success, and outreach to potential

²⁸⁸ Eccles (Scientia) 481:1-19.

²⁸⁵ PX2049 at 001 (Email from Olson (Surmodics) to erick@medtechmn.com, Oct. 19, 2022).

286

PX2098 at 002 (Surmodics email from Ventura to Xiong July 25, 2024).

287

Stern (Contego) 980:2-5; PX2261 at 01-02

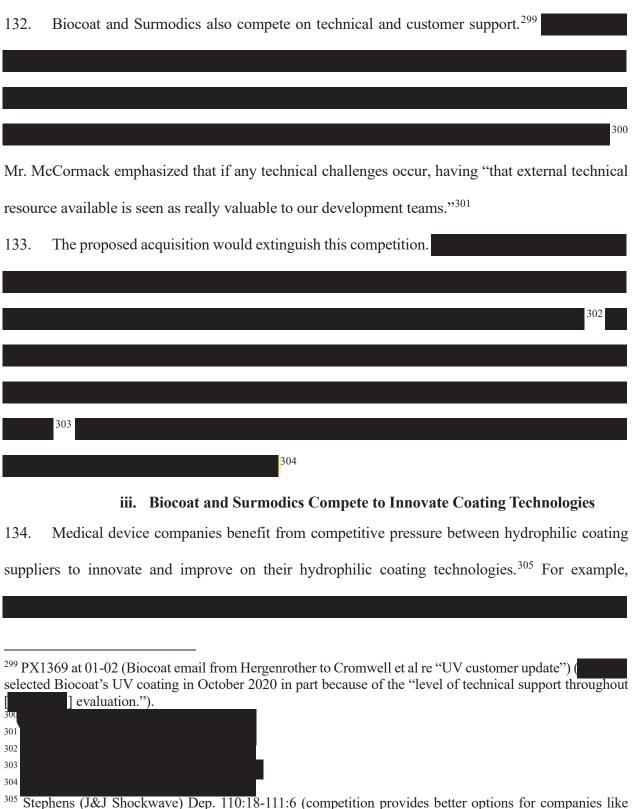
(Email from to Rudin, Coating Contract) (asked Surmodics

"[c] an you do a bit better on the pricing? Our current price at Biocoat is this request, Surmodics offered a lower price than they were initially going to quote

customers.²⁹⁰ In an email to Biocoat's Mr. Sandora in July 2024, Mr. de Freitas noted that a customer utilizing Surmodics "was not pleased with Surmodics lack of customer support[.]"291 Similarly, Surmodics understood that if they did not resolve coating challenges for could switch to Biocoat, resulting in to Biocoat."292 Surmodics "los[ing] a major 293 131. Biocoat and Surmodics compete on turnaround time for customers, matching each other's speed in returning medical devices with hydrophilic coatings applied.²⁹⁴ For hydrophilic coating customers, a faster turnaround time ²⁹⁵ For example, in 2024, compete with Surmodics, Biocoat "as a gesture to . . . address [concerns about turnaround times compared to their existing supplier (Surmodics)," matched Surmodics' turnaround times. 297 Mr. de Freitas explained, "Given the previous loss of opportunities to Surmodics due to turnaround time issues, this gesture is essential for retaining their business."²⁹⁸ ²⁹⁰ de Freitas (Biocoat) 532:13-21; 533:3-14. ²⁹¹ PX1437 at 001. ²⁹² PX2075 at 001 (Email from Ventura to Militello, June 19, 2024);

²⁹⁸ PX1445 at 001 (Email from de Freitas to Biocoat Orders, Oct. 9, 2024).

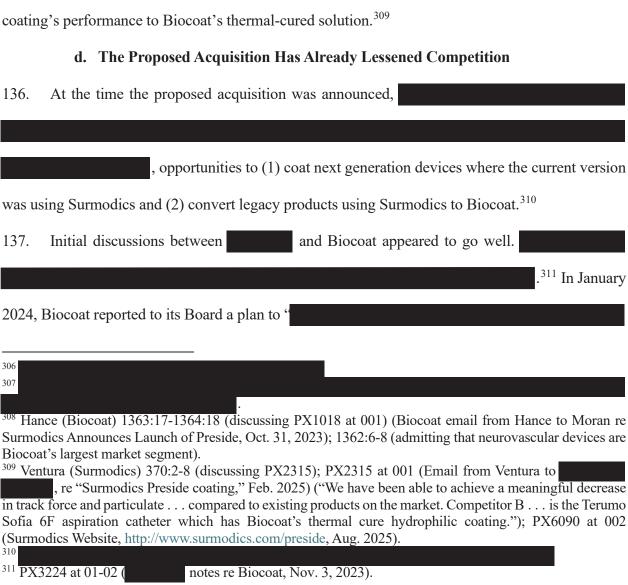
; PX1445 at 001 (Email from de Freitas to Biocoat Orders, Oct. 2024).

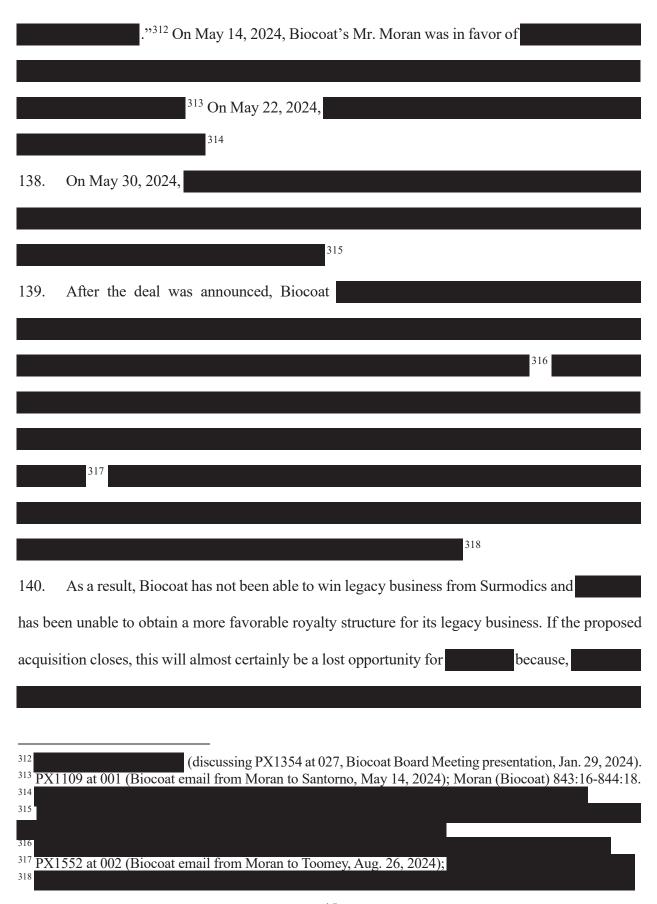


³⁰⁵ Stephens (J&J Shockwave) Dep. 110:18-111:6 (competition provides better options for companies like Shockwave that are looking to design and develop products); Eccles (Scientia) 482:21-483:5 (agreeing it is "important to Scientia to work with a hydrophilic coating supplier that has the ability to innovate" because "[w]e're going deeper in the brain every year . . . [T]hat helps a lot of patients. As we do that, we will need coatings that will advance the field and protect patients even better than they did before").



135. Biocoat's launch of its UV-cured solution and Surmodics' launch of its newest Preside coating are two examples of how customers benefit from innovation competition. When Surmodics launched its latest generation coating, Preside, in October 2023, Biocoat's Mr. Hance recalled a conversation with Surmodics' Mr. Olson, who said that Surmodics is "coming to get the Biocoat neurovascular business." Surmodics markets Preside to customers by comparing the coating's performance to Biocoat's thermal-cured solution.





IX. DEFENDANTS' PROPOSED REMEDY DOES NOT OFFSET THE LIKELY COMPETITIVE HARM OF THE PROPOSED ACQUISITION

- 141. Defendants ask the Court to bless their partial divestiture; however, as Dr. Fix concluded, Integer will not receive "the things that make Biocoat and Surmodics competitively significant."³²⁰ Defendants claim the divestiture would create a "near identical copy" of Biocoat, ³²¹ but Integer would pay less than 10% what GTCR paid for Biocoat in 2022, and the divestiture excludes the vast majority of Biocoat's customer contracts, coatings products, and employees. ³²²
- 142. Integer is not likely to replace lost competition from the merger; as detailed below in Sections IX.a–IX.g, because: (a) the divestiture excludes almost all existing business and customers; (b) the license back to Biocoat immediately weakens Integer's ability to compete and differentiate itself; (c) Integer has twice tried and failed to enter the hydrophilic coatings market; (d) Integer does not project meaningful revenue from new customer sales at any point in the near future and does not require such revenues to benefit financially from its agreement with Biocoat; (e) the divestiture does not include assets, personnel, and facilities necessary to enable Integer to compete; (f) the divestiture agreement entangles Integer with the merged firm; and (g) Integer's scale in other markets is irrelevant to assessing whether it will adequately offset the merger's harm.
- 143. Integer's hypothetical presence in the hydrophilic coatings market would not change that the proposed acquisition is presumptively illegal. Dr. Fix calculated the market share of the merged firm post-divestiture and found that GTCR would control of the relevant market, while Integer would have only market share.³²³

¹⁹

³²⁰ Fix 1145:14-1146:15.</sup>

³²¹ Defendants' Opening Argument 42:21-25.

³²² Marker (GTCR) 908:19-909:4; PFOF, *infra* ¶ 180-95.

³²³ PX4013 (Fix Rebuttal) ¶ 221, Figure 7.

- 144. Defendants and Dr. Wong assume that the details of the divestiture will work out,³²⁴ but customers in this industry note that the stablishes the flaws, risks, and customer concerns with the proposed divestiture.³²⁶ No third-party customer endorsed the proposed remedy or committed its hydrophilic coatings business to Integer.
- 145. Consistent with Integer's contractual obligation to "use reasonable best efforts to cooperate with the Seller in opposing (including by cooperating in litigation)," when asked about his opinions and intentions for the divestiture, Mr. Senn of Integer expressed optimism. 327 When asked, however, about verifiable facts, Mr. Senn was clear: Integer's size does not guarantee success; 328 Integer's tentative plans for the divestiture are dependent on future business circumstances and are not guaranteed; 329 and Integer does not have to sell a single new coating to profit from this deal. 330

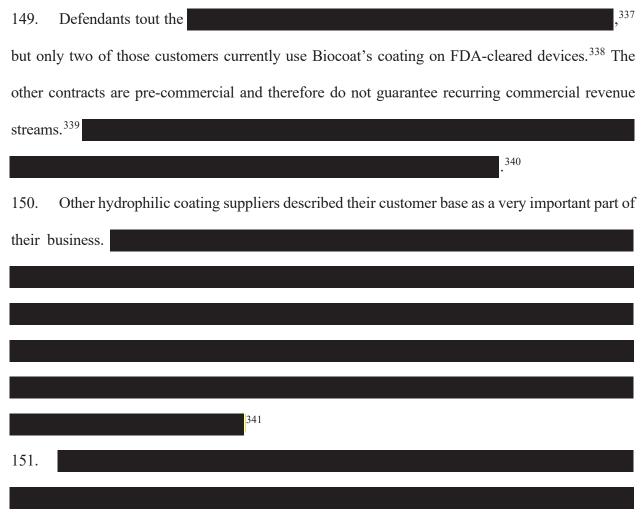
331 332

a. The Incumbent Hydrophilic Coating Supplier Has an Advantage When Competing for New Devices from Existing Customers

.333 .334

³²⁴ Wong 1643:4-16.
325
326 See PFOF, infra ¶ 148, 160-61.
327 See
328 Senn (Integer) 1781:24-1782:1
329 Senn (Integer) 1823:3-8.
330 Senn (Integer) 1831:21-1832:1.
331
332
333
334

148. No third-party customers testified that they intend to switch to Integer post-divestiture, and many of the Biocoat UV-cured coating customers included in the package must consent before their contracts can be transferred.³³⁵ Defendants and Integer provide no evidence that any Biocoat UV customers have consented to have their Biocoat contracts transferred to Integer.³³⁶



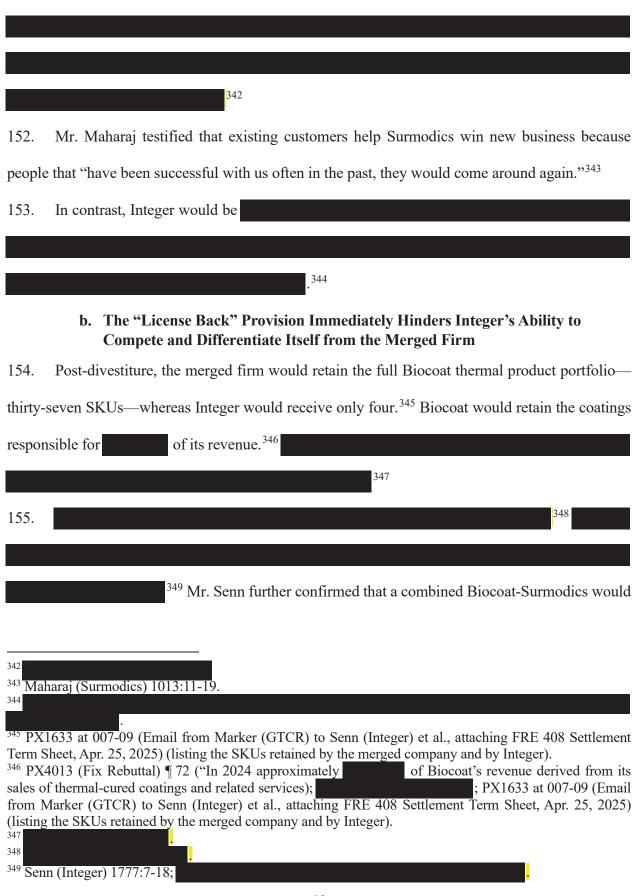
³³⁵ DX-020 at 011-12 (Disclosure Letter to the APA) § 4.04(b) (listing customers whose consent is needed before their contract can be transferred to Integer).

341

³³⁶ DX-020 at 011-12 (Disclosure Letter to the APA) § 4.04(b) (listing customers whose consent is needed before their contract can be transferred to Integer).

³³⁸ Hergenrother (Biocoat) 1432:17-23; 1433:11-13.

³⁴⁰



be able to offer customers a broader menu of coatings than Integer could. 350

156. ,351 but

Biocoat actively sells at least eight different thermal-cured topcoat variations, only two of which it would divest to Integer.³⁵² Biocoat's Application Development Manager, Elizabeth Green, testified that "[a] number of [older topcoats] are used on new devices today" and she does not "want to paint them into a legacy hole."³⁵³ These older topcoats are still in Biocoat's "wheelhouse."³⁵⁴

157. Biocoat tests multiple topcoats and basecoats—both new and legacy—to enable customers to find the best solution for their medical device.³⁵⁵ Post-merger, Biocoat will be the only supplier with the complete Biocoat thermal-cured coating portfolio to offer customers the option of legacy basecoats and topcoats in addition to the newest basecoats and topcoats.³⁵⁶

158. Though Defendants state Integer is receiving the "currently marketed" Biocoat thermal coatings,³⁵⁷

358

.)

PX3003 at 010, 013.

³⁵⁰ Senn (Integer) 1778:14-17.

³⁵¹ Schii (Hiteger) 1776.14-1

de Freitas (Biocoat) 509:7-23.

³⁵³ Green (Biocoat) Dep., 67:19-68:12; *see* Green (Biocoat) Dep. 65:6-65:19 (testifying "

³⁵⁴ Green (Biocoat) Dep. 67:19-68:12.

[;] de Freitas (Biocoat) 509:7-23; Green (Biocoat) Dep. 65:6-10.

³⁵⁶ de Freitas (Biocoat) 516:15-517:5.

159. Acquiring only some of Biocoat's topcoat formulations will hinder Integer's ability to compete with the merged firm. Mr. de Freitas of Biocoat testified that topcoat variations "are completely different chemistry compositions" such that he's "never seen a customer switch the chemistry." Mr. de Freitas admitted an existing Biocoat customer on a legacy thermal-cured topcoat would not switch to Integer selling a different thermal-cured topcoat. 361



- ____
- ³⁶¹ de Freitas (Biocoat) 511:2-4.

162.

³⁶⁰ de Freitas (Biocoat) 509:24-510:8.

c. Integer Previously Abandoned Its Own Hydrophilic Coating; the Divestiture Provides Neither the Assets nor the Incentives for Integer to Succeed Now

Mr. Senn testified that he expects Integer will be an effective outsourced hydrophilic coating

³⁶² 363 364

competitor on day one,³⁶⁵ but Integer already attempted to enter the hydrophilic coatings market and shut down the project,³⁶⁶ despite Integer being well-funded and having many of the same assets as today.³⁶⁷ After eight years of developing its own hydrophilic coating, Integer abandoned the effort as a "business decision" due to the additional "level of investment and the amount of market development needed."³⁶⁸

163. Integer stopped developing its own hydrophilic coating, even though "test results were actually fairly good," because Integer (i) "didn't think they were differentiated enough, versus... the other available coatings on the market"; (ii) "would have had to put some pretty significant investment into scaling the formulation of those coatings"; and (iii) "also just felt that being, kind of, competitive wasn't sufficient enough." Mr. Senn said, "we felt that, you know, the market development effort was too significant, coupled with the investment in, to scale it." 370

164. Dr. Wong testified that Integer's previous attempts to develop a hydrophilic coating were not successful because Integer could not develop a product with performance features that were "better than other available products."³⁷¹



³⁶⁵ Senn (Integer) 1725:18-24.

³⁶⁶ Senn (Integer) 1740:24-1741:10, 1776:8-1777:2.

³⁶⁷ Wong 1634:23-1635:12.

³⁶⁸ Senn (Integer) 1776:14-25.

³⁶⁹ Senn (Integer) 1741:11-1742:3.

³⁷⁰ Senn (Integer) 1741:11-1742:3.

³⁷¹ Wong 1634:23-1635:12 (emphasis added).

³⁷²

166. Mr. Senn testified that Integer intends to compete this time,³⁷⁴ but the same obstacles prompting Integer to abandon before still exist today: (i) Integer would possess an undifferentiated product, Biocoat's thermal-cured coating, sharing a license with the combined firm;³⁷⁵ and (ii)

Moreover, post-merger, Integer would be competing against a larger competitor with more market share and a larger established customer base than ever before in the merged firm. ³⁷⁷ And though Mr. Senn touted Integer's relationships within the medical device industry, ³⁷⁸ those same relationships proved ineffective during Integer's prior failed entry attempt: Integer unsuccessfully offered its previous hydrophilic coating to its largest existing customer before deciding that the project was not worth the investment necessary to scale it. ³⁷⁹

167. Other factors will also impede Integer's ability to succeed as a competitor where it previously failed. Customers testified that they do not view Integer as a hydrophilic coatings company, or as a company that is likely to innovate.

380

³⁷⁴ Senn (Integer) 1747:3-7.

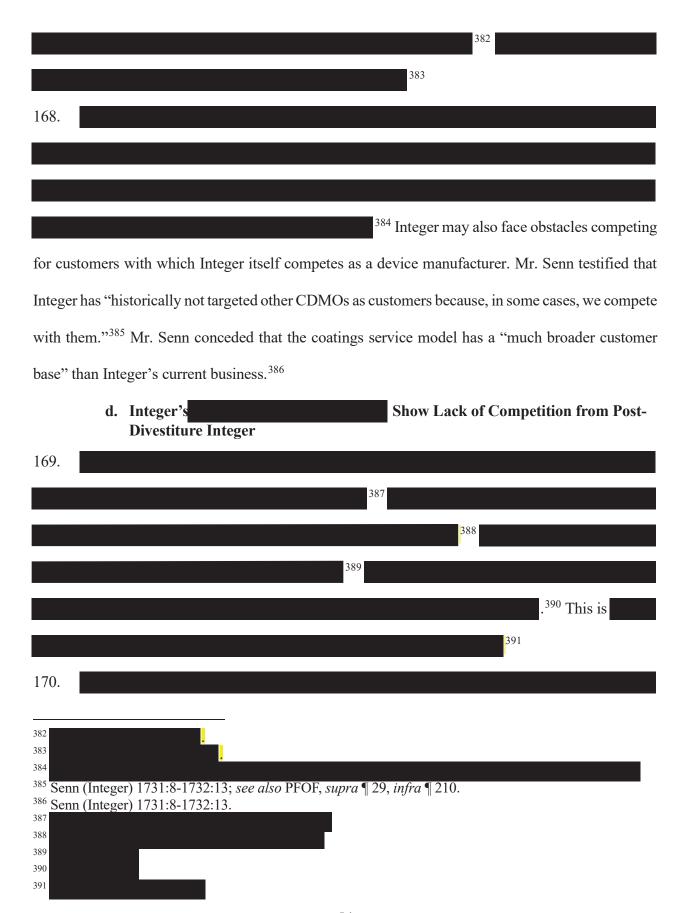
³⁷⁵ Senn (Integer) 1777:7-18.

PX4020 (Fix Rebuttal Figure 7).

³⁷⁸ Senn (Integer) 1735:3-19.

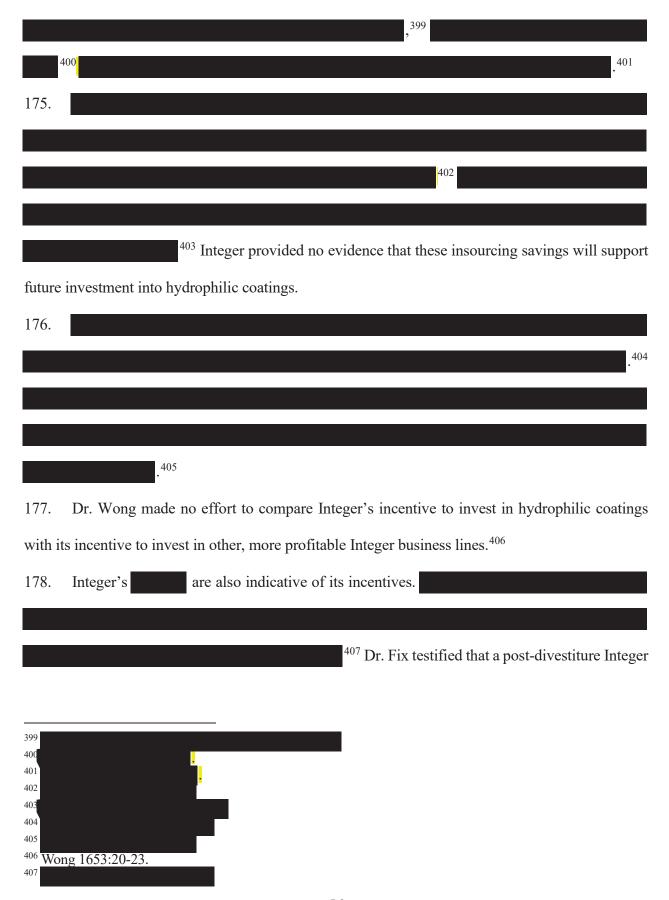
³⁷⁹ Senn (Integer) 1775:4-21: 1775:25-1776:2.

³⁸⁰ 381









per year without competing by insourcing the coatings it currently buys from Biocoat. In contrast, selling outsourced hydrophilic coatings would take time and investment. 408 Because Integer is acquiring one legacy thermal-cured coating it applies for its customers today, Integer is "going to get a lot of in-sourcing savings from that, assuming they start -- once they can make it, they'll be able to save a lot of money versus purchasing it from Biocoat."409

179.

410 Dr. Wong said that Integer's ability to profit from the partial divestiture without ever competing for new customers was "one of multiple benefits of the divestiture."411

e. The Proposed Partial Divestiture Excludes Key Assets, Employees, and Facilities That are Necessary to a Divestiture Buyer's Success

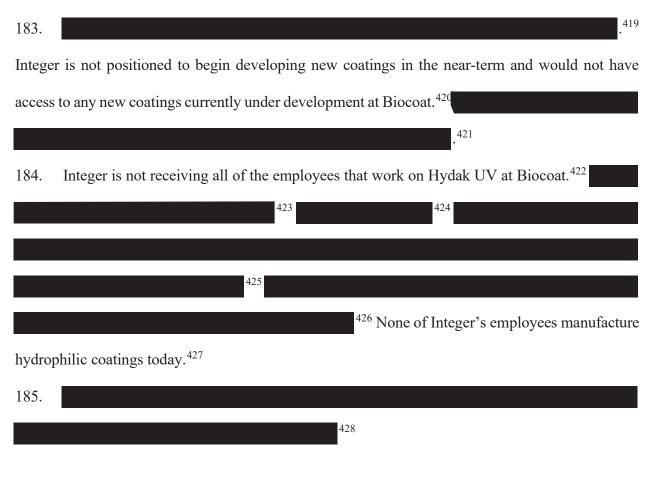


181. The price that Integer has offered to pay for the divestiture assets is less than 10% of what GTCR paid for Biocoat in 2022. 415



415 Marker (GTCR) 908:19-909:4.

416 417 The proposed divestiture does not include differentiated thermal-cured coatings, thermal-cured coating customer revenue streams, any thermal-cured coating customers, or the goodwill associated with Biocoat's reputation, as Biocoat will remain a separate competitor in the market. 418



⁴¹⁸ See generally DX-002; PX1633 (Email from Marker to Senn et al., attaching FRE 408 Settlement Term Sheet, Apr. 25, 2025).

[;] PX1633 at 003 ("Any post-divestiture product improvements by either the combined company or the divestiture buyer would not be provided to the other.").

⁴²⁰ Senn (Integer) 1779:11-1780:13; PX1633 at 003.

⁴²¹

⁴²² Hance (Biocoat) 1358:10-13.

⁴²³ Wong 1639:12-20.

⁴²⁵ DX-736 (Wong Report) ¶ 40.

Hergenrother (Biocoat) 1470:2-11 (Integer can't hire Dr. Long without his consent; and he does not know whether Mr. Menardi or Ms. Donnelly will go to the divestiture buyer).

⁴²⁷ Marker (GTCR) 900:1-7.

186. Mr. de Freitas, testified that Biocoat's team, including himself and Dr. Hergenrother, are critical to the sale of Biocoat's portfolio today. Ale Preitas Neither Mr. de Freitas nor Dr. Hergenrother is being transferred to Integer. Mr. de Freitas, who is responsible for selling the Hydak portfolio, testified he did not know whether Biocoat's UV-cured coating will be competitive if it is no longer sold by Biocoat's leadership and sales team, stating "I just don't know how it will perform." In 187. Dr. Hergenrother is the inventor of 22 patents and has worked on and brought to market several hydrophilic coatings during his time at Surmodics and at Biocoat. Dr. Hergenrother has relationships with customers spanning his over 20 years of experience in the hydrophilic coating industry and speaks to customers directly, working with them to develop and optimize the coating



on the medical device and to troubleshoot issues customers face. 433 Dr. Hergenrother was not

involved in establishing the scope of the divestiture package, including which personnel and assets

189. None of the employees proposed to be transferred from Biocoat to Integer have testified in this case. Nor have any of these individuals confirmed they intend to move to Integer. Integer hired a Ph.D. polymer chemist the last time it tried to enter the hydrophilic coatings market.⁴³⁷

would be included in the divestiture package. 434

⁴²⁹ de Freitas (Biocoat) 609:3-23.

⁴³⁰ de Freitas (Biocoat) 609:15-19:

⁴³¹ de Freitas (Biocoat) 608:10-609:2.

⁴³² Hergenrother (Biocoat) 1454:22-1455:5.

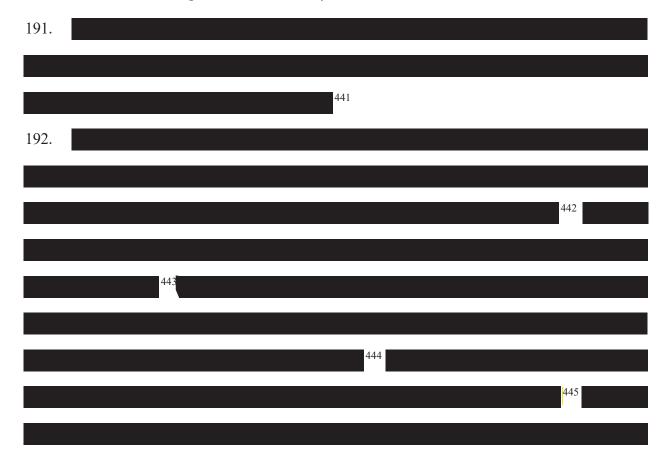
⁴³³ Hergenrother (Biocoat) 1456:8-20.

⁴³⁴ Hergenrother (Biocoat) 1440:15-17; 1446:3-7; 1475:22-1476:1-4.

⁴³⁶

⁴³⁷ Senn (Integer) 1740:24-1741:10.

190. Dr. Fix testified to the importance of employees to Integer's competitive success: "[E]mployees provide the competition. You can't compete without employees." Dr. Fix notes that, "All of the people who make strategic decisions about all of the dimensions of competition I talked about, those people would not be going to Integer. They're staying with Biocoat." Biocoat's witnesses Mr. de Freitas, Mr. Moran, Mr. Hance, and Dr. Hergenrother are all staying with Biocoat: "the institutional knowledge within Biocoat stays with Biocoat."



⁴³⁸ Fix 1153:20-1154:16.
439 Fix 1152:17-1154:16.
440 Fix 1152:17-1154:16.
441
442
443
444
445

193. The facility included in the divestiture is one where, today, Biocoat does not commercially manufacture hydrophilic coatings. 447 In contrast to the proposed divestiture, Integer's previous acquisition of a hydrophobic 194. coatings company, Precision Coating, included the entire company, including substantially all of its , products, 448 employees, full customer list, and a pipeline of new assets, customers. 449 Integer was able to begin operating the acquired company, Precision Coating, as a fully functioning business immediately after the acquisition was finalized. 450 195. Defendants have touted In the Matter of Boston Scientific / Guidant (2006) as a successful partial divestiture similar to what they proposed here, but Mr. Hance admitted that that divestiture is a "different situation than the divesture at hand[.]" Guidant was required to divest its entire vascular business, whereas here, 452 f. Post-Divestiture, Integer Would Be Reliant on Biocoat and Surmodics, With Whom It Is Expected to Compete 196. ⁴⁴⁷ Marker (GTCR) 901:13-17. ⁴⁴⁸ Senn (Integer) 1771:13-16 (Integer's purchase of Precision Coatings did not involve a license back for any

of the acquired products);

⁴⁴⁹ Senn (Integer) 1770:17-1771:12. 450 Senn (Integer) 1771:17-1772:5;

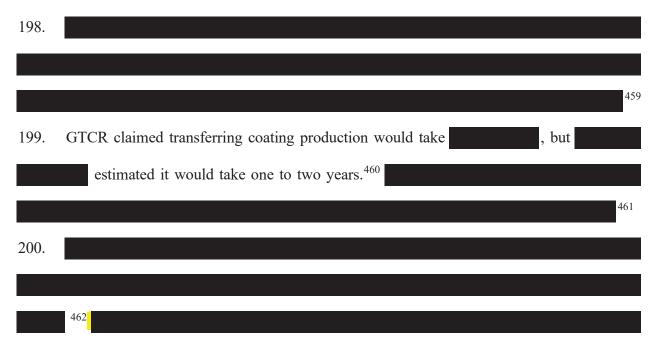
⁴⁵¹ Hance (Biocoat) 1355:21-1356:8; 1358:24-1361:8 (referring to PX6092 at 003-04 (Decision and Order, *In the Matter of Boston Scientific/Guidant*); 1361:20-22.

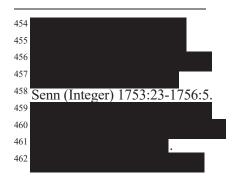
⁴⁵² Hance (Biocoat) 1355:21-1356:8; 1358:24-1361:8; 1361:20-22.

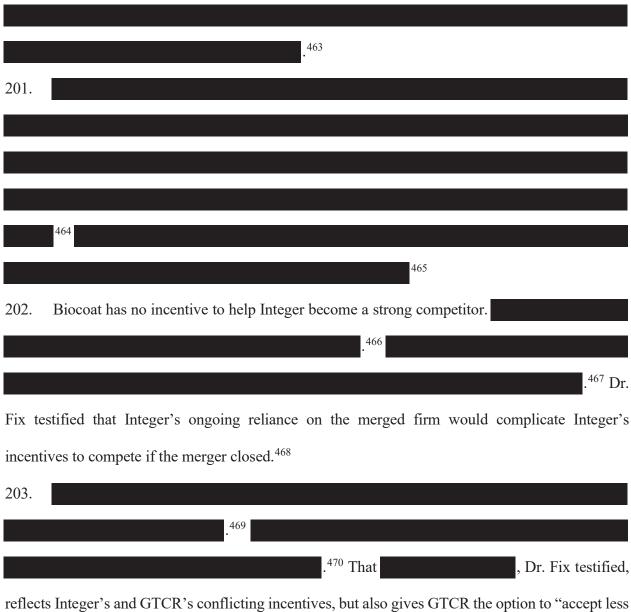
⁴⁵³

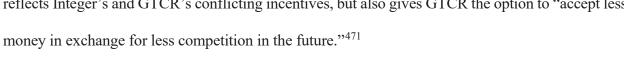


197. Integer will be reliant upon the merged firm to provide their newly purchased coatings to customers, since the technology transfer process and qualification and validation process will take time to complete. Integer must meet stringent quality standards, including equipment installation qualification, operational qualification, process qualification, and product performance qualification before it can even begin to develop and manufacture coatings. 458









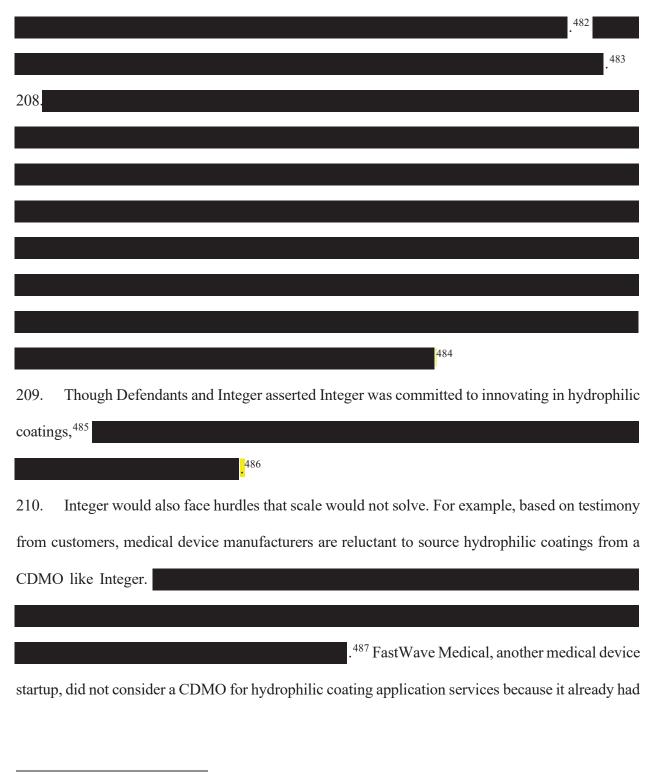


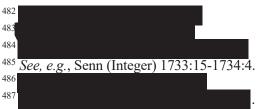
204. Integer also will remain reliant on the merged firm for key product inputs. Mr. Senn confirmed that a post-divestiture Integer would be both a customer and competitor of the merged entity for the foreseeable future. ⁴⁷² Integer will remain reliant upon Surmodics' hydrophilic coatings to supply its customers, as Surmodics' coatings are already used on FDA-approved medical devices. ⁴⁷³ Integer is not acquiring a license for all Biocoat coatings it currently purchases, so will "still depend on Biocoat for supply for their main business model." ⁴⁷⁴

g. Scale Isn't Enough – the Fact that Integer is a Large Company Does Not Automatically Position It for Success in Hydrophilic Coatings

205. Mr. Senn agreed that being a large, well-funded company does not guarantee success in the hydrophilic coatings market.⁴⁷⁵ 206. Despite being a large, well-funded international company with multiple facilities and thousands of employees, DSM was not able to meet Integer's performance criteria for its suppliers.⁴⁷⁷ 207. ⁴⁷² Senn (Integer) 1774:6-13. ⁴⁷³ Senn (Integer) 1772:22-1773:19. ⁴⁷⁴ Fix 1151:4-11. ⁴⁷⁵ Senn (Integer) 1781:24-1782:1. 477 Senn (Integer) 1780:18-1781:23. 479 480

481





a CDMO partner.⁴⁸⁸

211. Customers of hydrophilic coatings also place a premium on specific expertise developing and optimizing hydrophilic coatings, which, despite its size, Integer does not currently have. Although ,489 customers of hydrophilic coatings look beyond brand name to the actual company with expertise.490 Coatings are not sold off-the-shelf. Specialized engineers customize hydrophilic coatings to fit the specific requirements of each customer's device by adjusting several "process parameters."491 That service, called "application development,"492 is critical to the success of a hydrophilic coating supplier.493 Despite its experience tweaking and applying coatings in-house for many years, Scientia Vascular "would struggle" without application development services, which Mr. Eccles called "an art form."494

212. Reputation as an experienced, reliable supplier of hydrophilic coatings is important to customers, 495 competitors, 496 potential investors, 497 and Defendants themselves. 498 Biocoat and Surmodics built such reputations over the course of more than 30 years. 499 Integer does not have a similar reputation as a coatings company. 500 Indeed, one of the reasons Integer declined to invest in

⁴⁸⁸ Tieso (Fastwave) Dep. 143:18-144:11.

^{; 480:7-17 (&}quot;And so knowing that ISurTec's coating was the one that Harland was mostly applying, the coating experts were at ISurTec, so that's where we went and spent most of our time.");

⁴⁹¹ Ankeny (Harland) 208:4-23; Gronda (Medtronic) 723:2-724:3.

⁴⁹² de Freitas (Biocoat) 584:15-22.

⁴⁹³ Ankeny (Harland) 208:4-23.

⁴⁹⁴ Eccles (Scientia) 471:21-472:21.

⁴⁹⁵ Eccles (Scientia) 481:20-482:6;

⁴⁹⁶ Petra (DSM) 319:23-320:25,

⁴⁹⁸ de Freitas (Biocoat) 531:8-532:16; Maharaj (Surmodics) 1013:20-24.

⁴⁹⁹ Wong 1632:22-1633:8; PX4000 (Fix Report) ¶ 35.

⁵⁰⁰ Gronda (Medtronic) 725:11-20;

its own coating was Biocoat's and Surmodics' "strong reputation" in the coatings business. 501

- 213. Mr. Maharaj testified that the highly technical work of optimizing Surmodics' coatings on customers' devices requires "multiple sources of experience," "not just putting the coating on," and knowledge of Surmodics' technology is important to solving problems when they arise. 503
- 214. Choosing a hydrophilic coating supplier without the necessary expertise can cause significant delays in development and commercialization.⁵⁰⁴

X. DEFENDANTS OTHERWISE FAIL TO REBUT PLAINTIFFS' PRIMA FACIE CASE

a. Entry or Expansion is Unlikely to be Timely or Sufficient to Preserve Competition

215. Would-be entrants to the outsourced hydrophilic coatings market face significant barriers to entry. So Many "entry barriers are related to the qualification and the validation process of new [medical] devices. So Coating suppliers must "build a clinical track record and clinical proof" for each coating to gain customers, which "takes a long time . . . and it costs quite a lot of money. So The Established hydrophilic coating suppliers continue to face "high entry barriers in the market" when expanding their product offerings. So For example, DSM launched a new coating to expand its ComfortCoat portfolio around four to five years ago,

[509] Similarly,

[after only "

⁵⁰¹ Senn (Integer) 1741:11-1742:3.

⁵⁰² Maharaj (Surmodics) 1012:5-11.

⁵⁰³ Maharaj (Surmodics) 1012:22-1013:1.

⁵⁰⁴ PFOF, *supra* ¶ 95.

[;] Petra (DSM) 314:21-25, 316:16-23 (DSM has not seen many changes in the hydrophilic coatings industry in the past ten years due to high barriers to entry).

⁵⁰⁶ Petra (DSM) 318:1-5.

⁵⁰⁷ Petra (DSM) 317:12-318:5.

⁵⁰⁸ 509

interest from customers. 510

- 217. Smaller hydrophilic coating suppliers, like Hydromer, find it difficult to gain new customers and expand their business.⁵¹¹
- 218. The first major barrier to entry is product development. Development of a new hydrophilic coating requires years of research by highly specialized R&D teams.⁵¹²
- 219. Once the coating is developed, it can take years for hydrophilic coating suppliers to see meaningful adoption by customers.⁵¹³ Meaningful adoption by customers is slow because large medical device companies that use hydrophilic coatings typically select suppliers that they and have "

 "514 Specifically, medical device

manufacturers want to work with hydrophilic coating suppliers that have been used successfully on a device that has achieved regulatory clearance in the United States.⁵¹⁵

220. It is a lengthy and expensive process to establish a reputation as a reliable supplier among medical device companies. For example,

years and "several millions" to establish a reputation as a reliable supplier. ⁵¹⁷

221. Harland's CFO testified that

Torti (Hydromer) Dep. 196:18-197:10; 198:22-201:07, 263:23-264:05 (the outsourced hydrophilic coatings market is "dominated by three companies": Biocoat, Surmodics, and Harland, and noting "OEMs you know, many of them just aren't going to take a chance on someone who's not one of those three").

^{513 514}

[;] Torti (Hydromer) Dep. 142:23-143:17; Tieso (Fastwave) Dep. 65:9-66:1.

⁵¹⁷ Petra (DSM) 320:15-25.

518

- 222. Customers want to ensure their supplier will maintain continuity of supply and provide support over the life of a device. ⁵¹⁹ Customers have also found that past success with coating suppliers is more likely to lead to future success on other devices post-commercialization. ⁵²⁰
- 223. If a hydrophilic coating supplier has yet to go through the FDA regulatory process with a customer, large companies would "because they want to work with a supplier that has a history of FDA approval. 521 Even if such companies agreed to evaluate new coating suppliers, it would likely take years to do so. 522
- 224. Biocoat and Surmodics have earned a reputation as reputable, established hydrophilic coating suppliers. Biocoat's Mr. de Freitas, testified that this track record of clinical experience helps bring in new customers to Biocoat because customers care about whether a hydrophilic coating supplier has previously been included on an FDA-approved medical device. 523
- 225. Well-resourced suppliers struggled entering the hydrophilic coatings market. 524

b. Defendants Fail to Demonstrate Any Cognizable Efficiencies

226. Defendants have failed to establish that their claimed efficiencies are cognizable. ⁵²⁵ The only efficiency that has been preliminarily quantified is freight cost reductions, which were based on the estimates of a Biocoat employee and not independently verified. ⁵²⁶ Even if the full amount of the claimed efficiencies were credited as cognizable, that amount would be insufficient to offset the

[;] see also Stern (Contego) 970:17-975:8.

521
522
523 de Freitas (Biocoat) 531:6-533.
524 ; PFOF, supra ¶ 206.
525 PX4000 Fix Report ¶ 211-219; Hance (Biocoat) 1353:12-13, 1354:2-4, 1354:5-11, 1355:2-6.
526 Hance (Biocoat) 1353:1-7.

predicted anticompetitive harm to consumers. 527

227. Defendants have offered no procompetitive justifications for the merger. In fact, Defendants' executives admitted that the "[d]eal [was] not predicated on a bunch of synergies" and that this transaction will not expand nor improve the merged firm's business opportunities. 529

XI. EQUITIES FAVOR A PRELIMINARY INJUNCTION

- 228. If the proposed acquisition closes with the administrative trial pending, Defendants will immediately gain access to each other's competitively sensitive information.⁵³⁰ Additionally, Defendants' merger and partial divestiture to Integer will consummate, meaning medical device companies and patients will lose the benefits of competition between Surmodics and Biocoat and bear the risk that Integer will fail to vigorously compete.⁵³¹
- 229. Defendants' negligible claimed efficiencies (even if they were cognizable) would only be temporarily delayed during the pendency of the administrative trial.⁵³²
- 230. Pausing the proposed acquisition may postpone the return on investment for the "institutions and individuals who invest in the companies" Surmodics and Biocoat. 533

PLAINTIFFS' PROPOSED CONCLUSIONS OF LAW

I. Legal Standard

a. Section 7 of the Clayton Act

231. Section 7 of the Clayton Act, designed to halt harm from an anticompetitive merger "in its incipiency," bars mergers "the effect of [which] may be substantially to lessen competition, or tend

⁵²⁷ PX4000 Fix Report ¶ 215 ("Even if the Parties did provide sufficient verification for their claimed freight costs savings, they are too small to outweigh the significant anticompetitive effects that will likely arise from the Proposed Acquisition.").

⁵²⁸ Marker (GTCR) 873:17-24 (discussing PX1611).

⁵²⁹ de Freitas (Biocoat) 609:24-610:7.

⁵³⁰ Hance (Biocoat) 1322:21-1323:3 ("knowledge sharing" is part of the post-acquisition integration plan).

⁵³¹ See PFOF, supra ¶¶ 141-214; see also Fix 1160:1-21;

⁵³² See PFOF, supra ¶¶ 226-27.

⁵³³ Defendants' Closing Argument 1978:2-3.

to create a monopoly" in "any line of commerce" or activity affecting commerce in any section of the country. *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 589 (1957) (quoting 15 U.S.C. § 18).

- The Seventh Circuit recognizes that Section 7 necessarily "requires a prediction" and that in making that prediction "doubts are to be resolved against the transaction." *FTC v. Elders Grain, Inc.*, 868 F.2d 901, 906 (7th Cir. 1989); *see also Hosp. Corp. of Am. v. FTC*, 807 F.2d 1381, 1389 (7th Cir. 1986) ("A predictive judgment, necessarily probabilistic and judgmental rather than demonstrable, is called for."). Congress specifically chose the word "may" to convey "that its concern was with probabilities, not certainties." *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962).
- 233. Under Seventh Circuit precedent, the FTC need not establish a "certainty" or "even a high probability" of anticompetitive harm under Section 7. *Elders Grain*, 868 F.2d at 906; *see also FTC v. Advoc. Health Care Network*, 841 F.3d 460, 467 (7th Cir. 2016); *FTC v. OSF Healthcare Sys.*, 852 F.Supp.2d 1069, 1074 (N.D. Ill. 2012). "All that is necessary is that the merger create an appreciable danger of [anticompetitive harm] in the future." *Hosp. Corp. of Am.*, 807 F.2d at 1389. The cases cited by Defendants in their closing do not require otherwise.
- 234. Defendants ask the court to reject this standard, relying on *FTC v. Tempur Sealy Int'l, Inc.*, 768 F.Supp.3d 787 (S.D. Tex. 2025). But the *Tempur Sealy* court repudiated the principle articulated in *Elders Grain* based on its assessment that no binding precedent in the Fifth Circuit permitted that standard. *Id.* at 814. The Seventh Circuit, however, has directly endorsed that standard, *Elders Grain*, 868 F.2d at 906, and nothing in *Tempur Sealy* or Defendants' other cited cases permit this Court to ignore binding Seventh Circuit precedent.

b. Standard for Injunctive Relief (Section 13(b) of the FTC Act)

235. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes the FTC to obtain a preliminary

injunction "[u]pon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest."

- 236. "[T]o demonstrate such a likelihood of ultimate success, the FTC must raise questions going to the merits so serious, substantial, difficult and doubtful as to make them fair ground for thorough investigation, study, deliberation and determination by the FTC in the first instance and ultimately by the Court of Appeals." FTC v. Advoc. Health Care, 2017 WL 1022015, at *2 (N.D. Ill. Mar. 16, 2017) (citation omitted). "Although the district court may not 'simply rubber-stamp an injunction whenever the FTC provides some threshold evidence,' the FTC 'does not need detailed evidence of anticompetitive effect at this preliminary phase.' Instead, 'at this preliminary phase it just has to raise substantial doubts about a transaction." Advoc. Health Care, 2017 WL 1022015, at *2 (quoting OSF Healthcare, 852 F.Supp.2d at 1074).
- 237. Defendants' argument that the Section 13(b) standard requires Plaintiffs to *prove* that the proposed acquisition may substantially lessen competition directly contradicts long-standing precedent that courts "do not require the FTC to prove the merits of its case in a section 13(b) proceeding." *FTC v. IQVIA Holdings, Inc.*, 710 F.Supp.3d 329, 349 (S.D.N.Y. 2024) (collecting cases). "It is important to bear in mind that, when ruling on a request for a preliminary injunction pursuant to § 13(b), '[t]he district court is not authorized to determine whether the antitrust laws have been or are about to be violated. That adjudicatory function is vested in the FTC in the first instance." *OSF Healthcare*, 852 F.Supp.2d at 1073 (citation omitted).
- 238. Under Section 13(b), courts follow a two-step analysis to: (1) determine the Commission's likelihood of ultimate success on the merits; and (2) balance the equities to determine if preliminary relief serves the public interest. *Elders Grain, Inc.*, 868 F.2d at 902; *see FTC v. Penn State Hershey Med. Ctr.*, 838 F.2d 327, 337 (3rd Cir. 2016) (cleaned up).

239. Defendants' reliance on the higher standard set forth for other types of preliminary injunctions in *Starbucks Corp. v. McKinney*, 602 U.S. 339 (2024), is inapposite. The "Winter" test set forth in *Starbucks* has been rejected by other courts when analyzing Section 13(b), as the typical two-step analysis has been used "in antitrust cases for decades." *See FTC v. Kroger Co.*, 2024 WL 5053016, at *2 (D. Or. Dec. 10, 2024); *see also FTC v. H.J. Heinz Co.*, 246 F.3d 708, 714 (D.C. Cir. 2001); *FTC v. Exxon Corp.*, 636 F.2d 1336, 1343 (D.C. Cir. 1980). Indeed, Defendants concede that a showing of irreparable injury is not required under Section 13(b). *See* ECF 202 (Defendants Opposition to Motion for Preliminary Injunction) at 11.

c. Burden-Shifting Framework

- 240. Courts apply a burden-shifting framework to evaluate Section 7 claims. *OSF Healthcare*, 852 F.Supp.2d at 1074; *see United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990). Under this framework, plaintiffs must first establish a *prima facie* case that a proposed acquisition is unlawful. *See OSF Healthcare*, 852 F.Supp.2d at 1074. If plaintiffs establish a *prima facie* case, the burden of proof shifts to defendants to produce evidence showing that plaintiffs' evidence does not accurately depict the merger's likely competitive effects. *United States v. Marine Bancorp.*, *Inc.*, 418 U.S. 602, 631 (1974). If defendants meet their burden, the burden shifts back to plaintiffs to produce additional evidence of competitive harm. *OSF Healthcare*, 852 F.Supp.2d at 1075. The stronger the *prima facie* case, "the more evidence the defendant must present to rebut it successfully." *Heinz*, 246 F.3d at 725 (quotations omitted).
- 241. The Supreme Court has made clear that upon plaintiffs' establishment of a *prima facie* case, a presumption arises that the acquisition is anticompetitive. That presumption alone warrants a preliminary injunction, unless defendants can demonstrate procompetitive effects sufficient to overcome the presumption of anticompetitive harm. *See Baker Hughes*, 908 F.2d at 982 ("By showing that a transaction will lead to undue concentration in the market for a particular product in

a particular geographic area, the government establishes a presumption that the transaction will substantially lessen competition. The burden of producing evidence to rebut this presumption then shifts to the defendants.") (collecting Supreme Court cases).

242. Defendants have cited FTC v. RAG-Stiftung, 436 F.Supp.3d 278, 320 (D.D.C. 2020), for the proposition that Plaintiffs' case is unduly speculative because it fails to present evidence that Defendants intend to raise prices post-merger. To the contrary, that court noted that, "[o]f course, such a smoking gun is not necessary for the FTC to meet its burden." RAG-Stiftung, 436 F.Supp.3d 278, 320. As the Seventh Circuit recognizes, "Section 7 does not require proof that a merger or other acquisition has caused higher prices in the affected market." Hosp. Corp. of Am., 807 F.2d at 1389. 534 243. When defendants propose a remedy such as a divestiture, courts consider that remedy as part of defendants' rebuttal case, placing the burden on defendants to establish that their proffered remedy would nullify the anticompetitive effects that would otherwise result from the merger. See, e.g., Kroger, 2024 WL 5053016, at *24 ("Defendants bear the burden of showing that any proposed remedy,' including a divestiture, 'would negate any anticompetitive effects of the merger.") (citing FTC v. Staples, Inc., 190 F.Supp.3d 100, 137, n. 15 (D.D.C. 2016)); United States v. Aetna Inc., 240 F.Supp.3d 1, 60 (D.D.C. 2017) ("a defendant may introduce evidence that a proposed divestiture would 'restore [the] competition' lost by the merger....") (citations omitted); FTC v. CCC Holdings Inc., 605 F.Supp.2d 26, 46-47, 56-59 (D.D.C. 2009); United States v. Franklin Elec. Co., 130 F.Supp.2d 1025, 1026 (W.D. Wis. 2000).

244. Defendants incorrectly argue that Plaintiffs bear the burden of addressing Defendants' Proposed Remedy as part of Plaintiffs' *prima facie* case, relying on dicta from

⁵³⁴ In addition, some of the cases that Defendants rely on to argue that Plaintiffs' case is impermissibly speculative, such as *Tempur Sealy* and *Meta*, did not involve a presumption of illegality based on a showing that the proposed acquisition will lead to undue concentration in the market, as this case does. *See* PCOL, *infra* ¶¶ 287-299 (discussing presumption of illegality).

United States v. UnitedHealth Group Inc., 630 F.Supp.3d 118 (D.D.C. 2022). But when evaluating the horizontal theories of harm, the UnitedHealth court applied the traditional burdenshifting framework to conclude that the government was entitled to a presumption of reduced competition based on pre-divestiture market shares. Id. at 134. The court then required defendants to "prove in rebuttal that the proposed divestiture . . . will 'restore the competition lost by the merger." Id. at 135 (quoting Aetna, 240 F.Supp.3d at 60); see Tempur Sealy, 768 F.Supp.3d at 834 (considering "remedial commitments" such as a divestiture separate from the FTC's prima facie case). Sas Regardless, Plaintiffs would prevail no matter what step of the burden-shifting framework the divestiture is considered.

d. Evidentiary Value of Ordinary Course Documents

245. Contemporaneous business documents are among the strongest evidence in merger cases. *See, e.g., Chi. Bridge & Iron Co. v. FTC*, 534 F.3d 410, 433 (5th Cir. 2008) (finding government presented a "strong *prima facie* case" based on evidence "such as customer testimony, history of the market, and [the defendant's] internal documents"); *see also United States v. H&R Block, Inc.*, 833 F.Supp.2d 36, 52 (D.D.C. 2011). "Courts frequently rely on ordinary course documents and witness testimony illustrating that two merging parties view each other as strong competitors." *IQVIA*, 710 F.Supp.3d at 383; *see Kroger*, 2024 WL 5053016, at *19.

246. Ordinary course documents should be afforded substantially greater weight than defendants' self-serving attempts to minimize their plain meaning. *FTC v. Tapestry, Inc.*, 755 F.Supp.3d 386, 453 (S.D.N.Y. 2024) ("The Court finds these [ordinary course] documents to be more compelling

⁵³⁵ Defendants' reliance on *Arch Coal* and *Microsoft* to support their distorted burden-shifting framework is inapposite. In *Arch Coal*, the court considered the remedy evidence as part of "defendants' burden." *FTC v. Arch Coal*, Inc., 329 F.Supp.3d 109, 147 (D.D.C. 2004). *Microsoft*, a vertical merger case, involved unilateral behavioral commitments regardless of the outcome of the merger. *FTC v. Microsoft Corp.*, 681 F.Supp.3d 1069, 1090-91 (N.D. Cal. 2023).

evidence of commercial realities than the platitudes offered by Defendants' executives and experts."); see IQVIA, 710 F.Supp.3d at 385 (court was "more persuaded by the plain import of [Defendants'] contemporaneous statements as reflected in the documentary record than by Defendants' attempts to diminish the substantial evidence[.]"). The Supreme Court has long recognized the "extremely limited" value of evidence created while a lawsuit was "threatened or pending." United States v. Gen. Dynamics Corp., 415 U.S. 486, 504-05 (1974); Chi. Bridge, 534 F.3d at 434-35 (same). "[A] firm's behavior undertaken with the aim of persuading a court or the government regarding the legality of a merger may not be predictive of how that firm will behave once the court or the government are no longer engaged." Aetna, 240 F.Supp.3d at 80; see OSF Healthcare, 852 F.Supp.2d at 1087-88 (noting such evidence "adds little to the analysis"); see, e.g., PFOF, supra ¶ 22; 41; 49; 54-55; 68-71.

II. Relevant Antitrust Market

a. Product Market

- 247. Section 7 prohibits acquisitions that may "substantially lessen competition 'within the area of effective competition." *Brown Shoe*, 370 U.S. at 324.
- 248. The relevant product market is "any line of commerce" affected by the proposed merger. *Id.*The relevant market must "correspond with commercial realities of the industry." *OSF Healthcare*,
 852 F.Supp.2d at 1076-77 (quoting *Brown Shoe*, 370 U.S. at 336).
- 249. The purpose of defining a relevant product market is to identify "the functionally similar products to which customers could turn" in the event of a post-merger price increase. *FTC v. Peabody Energy Corp.*, 492 F.Supp.3d 865, 884 (E.D. Mo. 2020); *see H.J. Heinz*, 246 F.3d at 718 (products should only be included if "consumers regard the products as substitutes").
- 250. Defining a relevant market is not an end unto itself; rather, it is an analytical tool used to ascertain the "locus of competition." *United States v. Bertelsmann SE & Co.*, 646 F.Supp.3d 1, 24

- (D.D.C. 2022) (quoting *Brown Shoe*, 370 U.S. at 320-21).
- 251. "Courts consider both quantitative and qualitative evidence in defining the relevant product market." *IQVIA*, 710 F.Supp.3d at 353.
- 252. In a 13(b) proceeding, it is "not necessary" for plaintiffs "to *prove* the existence of the [relevant] market." *IQVIA*, 710 F.Supp.3d at 368 (cleaned up). Instead, plaintiffs need only "rais[e] some question of whether [the alleged market] is a well-defined market." *FTC v. Whole Foods Mkt.*, *Inc.*, 548 F.3d 1028, 1037 (D.D.C. 2008).
- 253. "A product market includes all goods that are reasonable substitutes, even though the products themselves are not entirely the same." *See FTC v. Sysco Corp.*, 113 F.Supp.3d 1, 24 (D.D.C. 2015); *see also FTC v. Staples Inc.*, 970 F. Supp. 1066, 1074 (D.D.C. 1997) (inquiry is "whether two products can be used for the same purpose, and if so, whether, and to what extent purchasers are willing to substitute one for the other"); *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559, 565 (6th Cir. 2014).
- 254. A product market's "outer boundaries" are determined by the "reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it. However, within this broad market, well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes." *Brown Shoe*, 370 U.S. at 325.
- 255. "[E]ven if alternative submarkets exist . . . the viability of such additional markets does not render the one identified by the government unusable." *Bertelsmann*, 646 F.Supp.3d at 28; *see IQVIA*, 710 F.Supp.3d at 368; *Tapestry*, 755 F.Supp.3d at 454 ("That there is a broad market . . . does not negate the existence of a [a smaller] relevant submarket[.]").
- 256. "Whatever the market urged by the [plaintiffs], the other party can usually contend plausibly that something relevant was left out, that too much was included, or that dividing lines between

inclusion and exclusion were arbitrary. The Supreme Court has wisely recognized there is some artificiality in any boundaries, but that such fuzziness is inherent in bounding any market." *FTC v. Tronox Ltd.*, 332 F.Supp.3d 187, 202 (D.D.C. 2018).

- 257. Defendants' implicit argument that there can be only one acceptable product market, and that it must be the narrowest possible market, directly contradicts both the plain text of the Clayton Act and established Supreme Court precedent. The Clayton Act prohibits an acquisition in "any line of commerce" that may "substantially . . . lessen competition, or tend to create a monopoly." 15 U.S.C. § 18 (emphasis added). It does not dictate any particular line of commerce. It also contradicts the Supreme Court's admonishment that market definition is a "pragmatic, factual" exercise rather than a "formal, legalistic" one. *Brown Shoe*, 370 U.S. at 336.
- Defendants' reliance on *Arch Coal* to justify their argument that only one, narrowest, market is permissible, is misplaced. The "narrowest market" principle articulated in *Arch Coal* simply instructs that the market definition exercise should begin narrowly and expand until the relevant market is identified. *FTC v. Arch Coal, Inc.*, 329 F.Supp.2d 109, 120 (D.D.C. 2004). *Arch Coal* does not suggest that the narrowest market is necessarily the only possible market. *Id.* Indeed, the Supreme Court has recognized a relevant market even where a narrower market might also exist and has rejected an "unduly narrow construction of . . . 'competition" that would "limit the competition protected by [Section] 7 to competition between identical products." *United States v. Continental Can Co.*, 378 U.S. 441, 452 (1964).
- 259. Plaintiffs may define a market in one of two ways: (1) using the *Brown Shoe* practical indicia, or (2) the "hypothetical monopolist test" or "HMT," either of which may be used to define a relevant market. *Beatrice Foods Co. v. FTC*, 540 F.2d 303, 308 (7th Cir. 1976) (applying *Brown Shoe* factors); *Advoc. Health Care*, 841 F.3d at 473 (applying the HMT to define a relevant product

market); IQVIA, 710 F.Supp.3d 329 at 354-69 (analyzing both Brown Shoe factors and HMT).

i. Brown Shoe Factors

- 260. In *Brown Shoe*, the Supreme Court set out "practical indicia" for defining a relevant product market: "(1) the industry or public recognition of the submarket as a separate economic entity, (2) the product's peculiar characteristics and uses, (3) unique production facilities, (4) distinct customers, (5) distinct prices, (6) sensitivity to price changes, and (7) specialized vendors." *Beatrice Foods Co.*, 540 F.2d at 308 (citing *Brown Shoe*, 370 U.S. at 325).
- 261. Not all of *Brown Shoe's* practical indicia are required to find a relevant market. *IQVIA*, 710 F.Supp.3d at 355 (citing *Staples*, 970 F.Supp. at 1075). The indicia must be "viewed in totality" and not in isolation. *FTC v. Surescripts*, *LLC*, 665 F.Supp.3d 14, 43 (D.D.C. 2023).
- 262. In applying *Brown Shoe*, "[o]rdinary course of business documents reveal the contours of competition from the perspective of the parties, who...may be presumed to 'have accurate perceptions of economic realities." *Aetna*, 240 F.Supp.3d at 21 (quotation omitted). As such, "[w]hen determining the relevant product market, courts often pay close attention to the defendants' ordinary course of business documents." *H&R Block*, 833 F.Supp.2d at 52.
- 263. The key question the *Brown Shoe* factors seek to answer is whether products are substitutable, and therefore belong in the same relevant market. *IQVIA*, 710 F.Supp.3d at 355 (citing *Sysco*, 113 F.Supp.3d at 27).
- 264. Courts evaluate *industry or public recognition of the market as a separate economic entity* because "courts assume that economic actors usually have accurate perceptions of economic realities." *Tapestry*, 755 F.Supp.3d at 430 (quotations omitted).
- 265. In assessing industry or public recognition, courts look to "the economic realities of the industry" as described by market participants. *Tronox*, 332 F.Supp.3d at 198. Here, industry recognition overwhelmingly points to an outsourced hydrophilic coatings market that includes both

UV-cured and thermal-cured coatings and excludes hydrophobic and in-house coatings. PFOF, *supra* ¶¶ 39-58.

- 266. Defendants criticize Plaintiffs' reliance on Defendants' own ordinary course documents. But Courts often credit strong ordinary course evidence over the "self-serving statements of the merging parties" made during litigation, *Tapestry*, 755 F.Supp.3d at 485, particularly when those documents are consistent with testimony from industry participants. *IQVIA*, 710 F.Supp.3d at 365 (citing *Peabody*, 492 F.Supp.3d at 894-95).
- 267. For the product's *peculiar characteristics and uses*, courts focus on the quality of a product and how it is used by customers. *See, e.g., Tapestry*, 755 F.Supp.3d at 418. Here, voluminous evidence supports that outsourced hydrophilic coatings, including both thermal-cured and UV-cured coatings, have peculiar characteristics and uses. PFOF, *supra* ¶¶ 18-21.
- 268. Defendants essentially argue that Plaintiffs must show "perfect fungibility" between Biocoat and Surmodics' products, but that is not what the law requires. *Tempur Sealy*, 768 F.Supp.3d at 815 ("perfect fungibility" is not required for products to be in the same market). Courts routinely find that products with similar "characteristics and uses" belong to the same market, even if they are not identical. *Illumina, Inc. v. FTC*, 88 F.4th 1036, 1050 (5th Cir. 2023) ("[T]wo products need not be identical to be in the same market; rather, the question is merely whether they are 'similar in character or use."").
- 269. Defendants also argue that UV-cured and thermal-cured hydrophilic coatings do not belong in the same market because they are not interchangeable for every possible use, such as inner diameters of medical devices. The Seventh Circuit has specifically rejected the argument that products should not be included in the same market merely because they are "interchangeable . . . for some but not all tasks." *Beatrice Foods*, 540 F.2d at 308. The Supreme Court has also rejected

this argument. In Continental Can, the court noted that "glass and metal containers have different characteristics which may disqualify one or the other . . . from this or that particular use," 378 U.S. at 450, but applied the Brown Shoe factors and concluded that "complete interindustry competitive overlap need not be shown" for them to be part of the same product market and reversed the district court's decision. Id. at 457. As the Supreme Court has held, the language of Brown Shoe was not "intended to limit the competition protected by [Section 7] to competition between identical products[.]" Id. at 452; see PFOF, supra ¶ 39-44 (explaining why UV-cured and thermal-cured hydrophilic coatings are reasonably interchangeable).

- 270. Defendants' argument that Plaintiffs' proposed product market should include hydrophobic and in-house coatings, is contrary to Seventh Circuit precedent evaluating the *Brown Shoe* factors, which has held, "[t]he mere fact that several products are limited substitutes for one another and thus form a broad product market is not dispositive of whether they form a relevant product market for antitrust purposes." Beatrice Foods, 540 F.2d at 308.
- Other courts likewise recognize that selected competition on the margin between the product 271. in the market and products outside of the market does not defeat a proposed product market. *United* States v. Visa U.S.A., Inc., 163 F.Supp.2d 322, 338 (S.D.N.Y. 2001), aff'd, 344 F.3d 229 (2d Cir. 2003) (even though there may be "some competition for customers among planes, trains, cars and buses, the reality is that airplane travel is a distinct product in which airlines are the principal drivers of competition."); H&R Block, 833 F.Supp.2d at 54 ("[W]hile providers of all tax preparation methods may compete at some level, this does not necessarily require that [they] be included in the relevant product market for antitrust purposes.") (quotations omitted); see PFOF, supra ¶¶ 45-58 (explaining why hydrophobic and in-house coatings are properly excluded from the relevant market). Defendants rely on language from *United States v. Sungard Data Sys., Inc.*, to support their

272.

argument that the relevant market must include in-house coatings. 172 F.Supp.2d 172 (D.D.C. 2001). In *Sungard*, the court found that in-sourced products should be included in the relevant market because the *Brown Shoe* factors, including evidence that defendants considered internal solutions "as their main competitive threat," supported a finding that they belonged in the same market. *Id.* at 188. That is not the case here, where industry recognition demonstrates that customers generally *do not* consider in-house coatings to be a viable alternative to outsourced hydrophilic coatings, *see* PFOF, *supra* ¶¶ 53-58, and there is no similar evidence that Defendants consider in-house coatings to be a major competitive threat. Moreover, "the relevant question concerns not just the hypothetical possibility of substitution, but whether customers do in fact exhibit a willingness to substitute" those products. *Tronox*, 332 F.Supp.3d at 200. Here, the evidence shows that customers do not view hydrophobic or in-house coatings as substitutes. *See* PFOF, *supra* ¶¶ 45-58.

273. Certain marginal customers choosing a product outside of the candidate market does not defeat Plaintiffs' proposed market definition. *See United States v. Rockford Mem'l Corp.*, 898 F.2d 1278, 1284-85 (7th Cir. 1990) (affirming the district court's geographic market definition even though "defendants point[ed] out correctly that the hospitals in the defendants' service area may not exhaust the alternatives open to the residents of that area[]"); *Advoc. Health Care*, 841 F.3d at 470 (even if some patients were willing to travel for care at a hospital outside of the proposed market, a "silent majority" of patients would not, "enabling anticompetitive prices increases"); *Tapestry*, 755 F.Supp.3d at 456 (a customer purchasing products in and out of the proposed market does not disprove the existence of a distinct submarket). Defendants' arguments to the contrary are "a misunderstanding of competition. No market fits the economist's model of perfect competition—implying an infinite number of sellers having identical costs, a perfectly homogeneous product, and perfectly informed buyers[.]" *Elders Grain*, 868 F.2d at 907.

- 274. In evaluating *distinct prices*, courts have found that "a substantial price difference," along with other factors, can bear on the definition of the product market. *Tapestry*, 755 F.Supp.3d at 423; *United States v. Aluminum Co. of Am.*, 377 U.S. 271, 277 (1964) ("[T]he price differential [between aluminum conduct and copper conduct products] further sets them apart [as distinct product markets]."). Here, very large price differences between hydrophilic coatings and hydrophobic coatings, and similar prices for UV-cured and thermal-cured coatings, support a relevant market of outsourced hydrophilic coatings. PFOF, *supra* ¶ 30-31; 51.
- 275. The *price-sensitivity* factor considers "the responsiveness of the sales of one product to price changes of the other"—also known as the cross-elasticity of demand. *Staples*, 970 F.Supp. at 1074. Here, evidence demonstrates that customers of hydrophilic coatings are price sensitive, but that they would not switch to *other* types of coatings, including in-house coatings, as a result of price increases for outsourced hydrophilic coatings. PFOF, *supra* ¶¶ 30; 32-35, 51.
- The *specialized vendor* factor considers whether the relevant market has "distinct customers that require specialized vendors that offer value-added services." *Staples*, 190 F.Supp.3d at 119. Here, evidence from customers, competitors, and Defendants confirms that customers value specialized suppliers whose "core competency" is manufacturing hydrophilic coatings and can provide related services such as feasibility testing and optimization. PFOF, *supra* ¶¶ 24-29.
- 277. For the *distinct customers* factor, courts look to whether the customers of those products have "distinct needs." *FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F.Supp.3d 27, 52 (D.D.C. 2018). Evidence and testimony in this case demonstrates that certain customers of hydrophilic coatings, such as neurovascular catheter manufacturers, have distinct needs. PFOF, *supra* ¶ 18-21, 36-38. Moreover, not *all* customers need to have distinct needs in order for the Court to recognize a relevant product market. *Tapestry*, 755 F.Supp.3d at 456 ("If distinct customers were dispositive of the *Brown*

Shoe analysis, there would be no need for the other six factors.").

- 278. For *unique production facilities*, courts have considered whether the products in the proposed market were manufactured in a different manner from other products. *See Beatrice Foods*, 540 F.2d at 308. Defendants have argued that UV-cured and thermal-cured hydrophilic coatings do not belong in the same product market because they are applied in different manners. However, application methods are not part of the *Brown Shoe* factors and do not dictate whether UV-cured and thermal-cured hydrophilic coatings are part of the same market. Moreover, Plaintiffs need not satisfy *every Brown Shoe* factor to define a relevant market. *See* PCOL, *supra* ¶ 261; *see also United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 246 (8th Cir. 1988) (holding sugar and high fructose corn syrup were "functionally interchangeable" despite differences in source and production).
- 279. "The three most relevant factors used to determine reasonable interchangeability are use, quality, and price." *Archer-Daniels-Midland*, 866 F.2d at 246; *see Heinz*, 246 F.3d at 711-12 (focusing on customer perception of product substitutability, not production method, to determine whether products belong to the same market). Here, those factors overwhelmingly support a relevant market of outsourced hydrophilic coatings. *See* PFOF, *supra* ¶¶ 18-21, 30-52 (evidence that use, quality, and price all support a relevant market of outsourced hydrophilic coatings)
- 280. In totality, the *Brown Shoe* factors support that outsourced hydrophilic coatings for medical devices in the United States is a relevant antitrust product market.

ii. Hypothetical Monopolist Test

281. Courts also define relevant product markets using the HMT, which asks whether a hypothetical firm that controls the entire candidate product market could "raise prices profitably a bit above competitive levels," also referred to as a SSNIP. *Advoc. Health Care*, 841 F.3d at 465. The HMT asks, assuming all products or services in the candidate market were controlled and sold by a monopolist, whether that hypothetical monopolist could profitably impose a SSNIP, typically a five

to ten percent price increase, on a product or service (if so, that is a relevant market), or whether customers would switch to alternative products or services, making such a price increase unprofitable (if so, the market is too narrow). *See, e.g., OSF Healthcare*, 852 F.Supp.2d at 1075.

- 282. Courts can use either qualitative or quantitative analysis to conduct an HMT. See, e.g., McWane, Inc. v. FTC, 783 F.3d 814, 829–30 (11th Cir. 2015); Tevra Brands LLC v. Bayer HealthCare LLC, 2024 WL 2261946, at *3–6 (N.D. Cal. May 16, 2024); In re Dealer Mgmt. Sys. Antitrust Litig., 581 F.Supp.3d 1029, 1057 (N.D. Ill. 2022) ("denying exclusion of expert's market definition as unreliable for fail[ing] to substantiate his conclusions under the SSNIP test using empirical analysis where his opinions ha[d] a foundation in qualitative data such as employee testimony, third-party industry analyses, and media coverage.") (quotation omitted).
- 283. Defendants' implicit argument that an HMT is unreliable if more than one market could satisfy the HMT is contrary to both the language of the Clayton Act and Supreme Court precedent. PCOL, *supra* ¶¶ 255-58 (collecting case law that there can be more than one relevant market).
- 284. Proffered HMT calculations should be accepted when they are "at least somewhat indicative of likely diversion ratios" and defendants fail to put forward any alternative product market or HMT. *United States v. Bazaarvoice, Inc.*, 2014 WL 203966, at *32 (N.D. Cal. Jan. 8, 2014) (accepting plaintiff's HMT despite data limitations because the calculations "sufficiently reflected the state of the market" and where defendants failed to offer their own HMT); *see H&R Block*, 833 F.Supp.2d at 62; *Tapestry*, 755 F.Supp.3d at 451.
- 285. The market for outsourced hydrophilic coatings for medical devices in the United States satisfies the HMT. *See* PFOF, *supra* ¶¶ 59-63.

b. Geographic Market

286. The relevant geographic market is "where . . . the effect of the merger on competition will be direct and immediate" and "must correspond to the commercial realities of the industry." *Advoc*.

Health Care, 841 F.3d at 468 (quotations omitted). A relevant "geographic market does not need to include all of the firm's competitors; it needs to include the competitors that would substantially constrain [the firm's] price-increasing ability." *Id.* at 469. Here, the relevant geographic market is the United States. *See* PFOF, *supra* ¶ 64-66.

III. Proposed Acquisition's Effect on Competition

a. The Proposed Acquisition Is Presumptively Illegal

- 287. In *Philadelphia National Bank*, the Supreme Court held that "a merger which produces a firm controlling an undue percentage share of the relevant market, and results in a significant increase in the concentration of firms in that market is so inherently likely to lessen competition substantially that it must be enjoined in the absence of evidence clearly showing that the merger is not likely to have such anticompetitive effects." 374 U.S. 321, 363 (1963).
- 288. Under this precedent, plaintiffs establish a presumption that the proposed acquisition will substantially lessen competition "[b]y showing that the proposed transaction . . . will lead to undue concentration in the market[.]" *Staples*, 970 F.Supp. at 1083; *see also Heinz*, 246 F.3d at 715.
- 289. Plaintiffs can also establish a presumption that the proposed acquisition will substantially lessen competition by showing that the merged firm will have a market share of greater than 30%. *Phila. Nat'l Bank*, 374 U.S. at 364 ("Without attempting to specify the smallest market share which would still be considered to threaten undue concentration, we are clear that 30% presents that threat."); *see IQVIA*, 710 F.Supp.3d at 378-79.
- 290. The standard measure of market concentration is a statistical measure known as the Herfindahl-Hirschman Index ("HHI"). *See Kroger*, 2024 WL 5053016 at *15. The HHI for a market is calculated by summing the squares of the individual firms' market shares. *Id*.
- 291. The Merger Guidelines issued jointly by the U.S. Department of Justice and the Federal Trade Commission explain that a market is highly concentrated when it has an HHI greater than

1,800. 2023 Merger Guidelines § 2.1.⁵³⁶ A merger is presumptively unlawful when it increases a market's HHI by more than 100 and results in either (a) post-merger market share greater than 30% or (b) post-merger HHI exceeding 1,800. *Id*. These presumption thresholds have been endorsed by courts. *See, e.g., Heinz*, 246 F.3d at 716; *IQVIA*, 710 F.Supp.3d at 378; *CCC Holdings*, 605 F.Supp.2d at 37-38; *Kroger*, 2024 WL 5053016, at *15-16.

292. The 1,515 point increase in market concentration that Dr. Fix found would result from this transaction is substantially higher than other cases in which the government has successfully demonstrated its *prima facie* case. *See, e.g.*, *Heinz*, 246 F.3d at 716 (510 point increase); *FTC v. Univ. Health Inc.*, 938 F.2d 1206, 1211 n.12 (6th Cir. 1991) (630 point increase); *FTC v. PPG Indus.*, *Inc.*, 798 F.2d 1500, 1502-03 (D.C. Cir. 1986) (1,352 point increase); *H&R Block*, 833 F.Supp.2d at 72-73 (approximately 400 point increase); *FTC v. Cardinal Health, Inc.*, 12 F.Supp.2d 34, 53-54 (D.D.C. 1998) (increase of 629 to 1,733 points depending on market definitions); *see also* PFOF, *supra* ¶ 97 (Dr. Fix found that the market for outsourced hydrophilic coatings in the United States has a pre-merger HHI of 2,483, indicating that the market is already highly concentrated, and that the proposed acquisition would increase the market concentration by 1,515 points, resulting in a post-merger HHI of 3,998).

293. Dr. Fix's finding that, based on 2024 revenues, the merged firm would have a market share of 60.4%, PFOF, *supra* ¶ 97, or, taking into account Integer's hypothetical presence in the market, 57.6%, PFOF, *supra* ¶ 143 exceeds the threshold for a presumption of illegality. *See* PCOL, *supra* ¶ 287-99. These post-merger market shares are consistent with cases in which courts have found that the government established its *prima facie* case. *See OSF Healthcare*, 852 F.Supp.2d at 1078

⁵³⁶ Although the Merger Guidelines are not binding on courts, courts have routinely relied on them as persuasive authority. *See Kroger*, 2024 WL 5053016 at *16 ("In the short time in which the 2023 Merger Guidelines have been in effect, multiple courts have cited them as persuasive authority[.]") (collecting cases).

(59.4% combined share would "far surpass the threshold found to be presumptively unlawful"); *Univ. Health*, 938 F.2d at 1219 (43% combined share "clearly established a *prima facie* case of anticompetitive effect"); *ProMedica*, 2011 WL 1219281, at *12 (58.3% combined market share was presumptively anticompetitive "[b]y a wide margin").

- 294. Defendants have criticized Dr. Fix's use of revenues to measure market share as improperly backward looking. But revenue is a well-established basis for measuring market share in many different product markets. *See, e.g., Tapestry*, 755 F.Supp.3d at 457 (luxury handbags); *IQVIA*, 710 F.Supp.3d at 379-82 (healthcare digital advertising); *United States v. Energy Sols., Inc.*, 265 F.Supp.3d 415, 440-41 & n.16 (D. Del. 2017) (nuclear waste disposal); *Staples*, 970 F.Supp. at 1081-83 (sale and distribution of office supplies); *Sysco*, 113 F.Supp.3d at 56 (specialty food distribution channels); *CCC Holdings*, 605 F.Supp.2d at 45 (auto repair estimate software).
- 295. Merger review requires assessing the likely effect of the merger on competition; revenue is often the "best available predictor of future competitive significance." *IQVIA*, 710 F.Supp.3d at 390. Revenue is a superior basis for measuring market share—as opposed to simply counting the number of opportunities—where, as here, business opportunities are "not created equal." *Wilhelmsen*, 341 F.Supp.3d at 61. In industries where different business opportunities come from differently sized customers, focusing on "just the number of [business opportunities] obscures this fact, while using revenue data acknowledges that capturing the market for larger [business opportunities] means capturing a larger part of the market." *Id.* at 60-61; *see Beatrice Foods*, 540 F.2d at 312.
- 296. Defendants' reliance on *United States v. General Dynamics*, to argue that revenue is not a proper measure of market share here, is misplaced. In *General Dynamics*, the court found that future competition between the merging parties centered on the amount of unmined coal reserves that could be used to supply future customers and that existing coal production had no relationship with those

coal reserves. 415 U.S. at 501-02. In this case, there are no such capacity constraints, as the ability to provide hydrophilic coatings in the future is not linked to a supply of coal or other non-renewable resources. Moreover, testimonial and documentary evidence all make clear that Surmodics and Biocoat are still the two largest players in the outsourced hydrophilic coatings market and that they vigorously compete for new customers. *See* PFOF, *supra* ¶¶ 22, 71, 104.

297. General Dynamics also makes clear that revenue is an appropriate measure of market share and "future competitive strength" in markets where reputation and "brand recognition" are important criteria for customers. 415 U.S. at 501; see Bertelsmann, 646 F.Supp.3d at 20, 52 (finding in publishing industry, where reputation is important, "market shares are built on 'decades of credibility and success,' and they cannot be easily challenged by less-established publishers") (cleaned up); H&R Block, 833 F.Supp.2d at 75 (finding stable market shares consistent with "the importance of reputation and brand"). In the outsourced hydrophilic coatings market, past revenue is a direct proxy for a coating supplier's reputation and its ability to work with successful, FDA-cleared medical devices, which is an important factor for customers. See PFOF, supra ¶ 212-14; 222-24.

298. Defendants' alternative market share calculations that use FDA filings as a proxy for opportunities data improperly predict competitive dynamics dramatically at odds with the market realities described in both witness testimony and Defendants' ordinary course documents. *Cf. Energy Sols.*, 265 F.Supp.3d at 440 n.16 (rejecting opportunity-based market share estimate because it produced "a result that does not best reflect market realities"). Here, multiple third-party witnesses and Defendants' own documents recognize Biocoat and Surmodics as the top two competitors in the market, and there is no evidence to suggest that firms other than Biocoat and Surmodics comprise 78% of the market, as Dr. Wong suggests. *See* PFOF, *supra* ¶¶ 112-21. *See also* PFOF, *supra* ¶¶ 105-09 (explaining why Dr. Wong's reliance on this data is methodologically unsound).

299. Neither market concentration nor market share must be calculated with great precision; reasonable approximations based on the available data will suffice. *See Sysco*, 113 F.Supp.3d at 54 ("The FTC need not present market shares and HHI estimates with the precision of a NASA scientist. The closest available approximation often will do.") (cleaned up). By any reasonable measure, the merger of Biocoat and Surmodics is presumptively anticompetitive. *See* PFOF, *supra* ¶¶ 96-140.

b. The Proposed Acquisition Eliminates Substantial Head-to-Head Competition

A merger that eliminates head-to-head competition between two companies alone "may 300. substantially lessen competition" in violation of Section 7 and be sufficient grounds for a preliminary injunction. See ProMedica, 749 F.3d at 568-70 ("[T]he elimination of competition between two firms that results from their merger may alone constitute a substantial lessening of competition"); United States v. Mfrs. Hanover Trust Co., 240 F.Supp.867, 955 (S.D.N.Y. 1965) ("[T]he elimination of substantial competition previously existing between the parties to this merger in the national market itself... establishes a reasonable probability of a substantial lessening of competition, violative of § 7 of the Clayton Act."); Tapestry, Inc., 755 F.Supp.3d at 486 (quoting Sysco, 113 F.Supp.3d at 61) ("Courts have recognized that a merger that eliminates head-to-head competition between close competitors can result in a substantial lessening of competition."); 2023 Merger Guidelines § 2.2. Loss of head-to-head competition between merging parties may be enough enjoin a merger without the need to formally define a market. See Whole Foods, 548 F.3d at 1036 n.1. 301. Courts routinely find that the elimination of head-to-head competition between two of the top firms in a market may result in anticompetitive effects. See, e.g., Sysco, 113 F.Supp.3d at 65 (finding a proposed merger "between the number one and number two competitors" was likely to lead to unilateral anticompetitive effects); IQVIA, 710 F.Supp.3d at 377; H&R Block, 833 F.Supp.2d at 81-82; Staples, 970 F.Supp. at 1082-83; cf. Whole Foods, 548 F.3d at 1043 (Tatel, J., concurring)

("[T]here can be little doubt that the acquisition of the second largest firm in the market by the largest firm in the market will tend to harm competition in that market.").

302. The elimination of substantial head-to-head competition between Surmodics and Biocoat violates Section 7 of the Clayton Act. *See* PFOF, *supra* ¶¶ 111-25; *United States v. Blue Bell, Inc.*, 395 F.Supp. 538, 548-549 (M.D. Tenn. 1975) (citations omitted) (recognizing that when two companies are "vigorous, substantial and major factors in competition generally . . . the elimination of competition between them violated the Clayton Act"). It also demonstrates the anticompetitive effects of the proposed acquisition in the market for outsourced hydrophilic coatings in the United States. PFOF, *supra* ¶¶ 126-40.

IV. Defendants Cannot Rebut Plaintiffs' Prima Facie Case

303. Once Plaintiffs satisfy their *prima facie* burden, the burden shifts to Defendants to rebut Plaintiffs' case. *IQVIA*, 710 F.Supp.3d at 389. "[T]he more compelling the prima facie case, the more evidence the defendant must present to rebut it successfully." *Heinz*, 246 F.3d at 725; *see also OSF Healthcare*, 852 F.Supp.2d at 1082 (a compelling *prima facie* case "make[s] it more difficult for defendants to overcome the strong presumption of illegality that has arisen . . . "). To rebut Plaintiffs' *prima facie* case, Defendants must provide evidence beyond the unenforceable promises of their executives. *See Bertelsmann*, 646 F.Supp.3d at 50 (giving "no weight" to merging parties' "unenforceable promise" partly because "the promise can be broken at will . . . A unilateral promise by [a party] that it will not use its market power if it acquires [the other party] cannot rebut the government's prima facie case."); *Kroger*, 2024 WL 5053016, at *24 ("Despite defendants' best intention to follow through on their promises at this moment, the business realities on the ground after the merger may change what defendants are able to invest or what is in their best interest to invest.").

a. The Proposed Partial Divestiture Does Not Address the Acquisition's Anticompetitive Harm

i. Legal Standard

Where, as here, a divestiture is proposed to *remedy* the likely anticompetitive effects of a merger, Defendants must demonstrate that the divestiture "would restore the competition lost by the merger counteracting the anticompetitive effects of the merger." *Aetna*, 240 F.Supp.3d at 60 (quoting *Sysco*, 113 F.Supp.3d at 72) (cleaned up). "In other words, the divestiture must 'replac[e] the competitive intensity lost as a result of the merger." *Id.* (quoting *Sysco*, 113 F.Supp.3d at 72) (emphasis in original); *see also Kroger*, 2024 WL 5053016, at *24 ("Defendants bear the burden of showing that any proposed remedy,' including a divestiture, 'would negate any anticompetitive effects of the merger.") (quoting *Staples*, 190 F.Supp.3d at 137 n.15).

305. The more lenient standard advocated by Defendants, that the proposed remedy must "sufficiently *mitigate*[] the merger's effect such that it [is] no longer likely to *substantially* lessen competition[,]" *Illumina*, 88 F.4th at 1059, should not be adopted by this Court. "There are strong public interests in ensuring the effective enforcement of antitrust laws and in equipping the FTC with the ability to order appropriate remedies[,]" and these interests should not be discarded in the service of Defendants' tardy, self-serving proposal. *Tronox*, 332 F.Supp.3d at 219. In any event, the choice of standard does not affect the bottom line: Plaintiffs prevail even under Defendants' standard. *See* PCOL, *infra* ¶ 306-19.

ii. The Divestiture Must Create an Effective Competitor

306. Courts evaluate whether a divestiture would restore competition lost from the merger by examining a number of factors, including (1) the scope of the divestiture, including assets, facilities, and customer relationships; (2) the divestiture buyer's past experience in the relevant market; (3) any continued entanglement between the divestiture buyer and the merged firm; and (4) purchase price.

See Aetna, 240 F.Supp.3d at 60-74; *Sysco*, 113 F.Supp.3d at 72-78.⁵³⁷ The purpose of these factors is to assess whether a divestiture would create a new competitor that has both the means and incentive to compete effectively against the merged firm. *See Aetna*, 240 F.Supp.3d at 60.

307. In this inquiry, intent to compete does not imply competitive significance. Despite the divestiture buyer's "best intentions" to compete, it ultimately will yield to "the business realities on the ground" and "what is in [its] best interest." *See Kroger*, 2024 WL 5053016, at *24 (explaining why Defendants' promises were ultimately unenforceable). *See* PFOF, *supra* ¶¶ 162-68 (discussing Mr. Senn's testimony and Integer's incentives).

308. In *Sysco*, the court found that a proposed divestiture was not likely to maintain "the premerger level of competition that characterizes the present marketplace" despite a private equity divestiture buyer's commitment to spend a certain amount of money to develop the business and despite the experience of its executives in the industry. 113 F.Supp.3d at 73. The *Sysco* court did not doubt the financial commitment or the executives' leadership abilities, but nonetheless was "not persuaded that post-merger PFG will be able to step into USF's shoes to maintain—certainly not in the near term—the pre-merger level of competition that characterizes the present marketplace." *Id.* In reaching this conclusion, the *Sysco* court noted that based on the divestiture buyer's projected sales, it would capture "less than *half* of [the current company's] national customer sales in five years," indicating that it would not be "sufficiently able to discipline a merger-generated increase in market power." *Id.* at 73-74 (citation omitted) (emphasis in original). *See also* PFOF, *supra* ¶ 142, 147 (divestiture revenue predictions).

⁵³⁷ Defendants have relied on the factors set forth in *United States v. UnitedHealth Group Inc.*, 630 F.Supp.3d 118 (D.D.C. 2022). The factors set out in that case demonstrate that Defendants' proposed remedy here would not restore competition lost as a result of the merger. *See* PCOL, *supra* ¶¶ 306-19. Moreover, as the *UnitedHealth* court noted, the key question is whether the proposed remedy would "restore the competition lost by the merger." *Id.* at 135 (quoting *Aetna*, 240 F.Supp.3d at 60).

309. The relevant question is whether the divestiture puts the buyer in a position to compete effectively in the marketplace and constrain the merged firm. *See CCC Holdings*, 605 F.Supp.2d at 59 ("Whatever [divestiture buyer's] plans and aspirations for the future may be, it is very unlikely to be able to compete effectively[.]"); *UnitedHealth*, 630 F.Supp.3d at 137 ("[T]he question is whether [the buyer] will preserve competition in the relevant market, not whether [it] has a general incentive to maximize its return on investment."); *Sysco*, 113 F.Supp.3d at 73 (relevant inquiry is whether divestiture buyer will be able to "discipline a merger-generated increase in market power") (citation omitted).

- 1. The Scope of the Divestiture Does Not Position Integer to Compete Effectively
- 310. Divestitures should generally encompass an entire standalone business or product line—including all personnel, facilities, equipment, and other assets that are vital to the success of the business or product line—rather than pieces of a business that may not succeed without the whole. *Kroger*, 2024 WL 5053016, at *26 (rejecting divestiture that did "not represent a standalone, fully functioning company"); *see also Sysco*, 113 F.Supp.3d at 74 (considering whether facilities included as part of divestiture would enable a buyer to compete with the merged firm); *id.* at 76 (considering "disadvantages" the divestiture buyer would face from having less than half the salespeople of the existing business and noting, "fewer SKU offerings will be a competitive disadvantage.").
- 311. To increase the likelihood of success, a divestiture should include a sufficient number of existing customers, so the divestiture buyer is not left to build the business "essentially from scratch." *Aetna*, 240 F.Supp.3d at 65 (explaining concerns that as part of divestiture, buyer would not acquire provider contracts). Indeed, nearly all of the past divestitures Defendants attempt to analogize to their proposal either (1) required the transfer of all customer contracts related to the divested assets

or (2) prohibited the merged firm from retaining any customers or revenues. 538

- The necessity of a standalone business or product line is not theoretical; it is meant to assess the likelihood of a divestiture buyer's success. Standalone businesses or product lines have already proven to be successful in the market. Partial divestitures, such as the one proposed here, therefore "increase[] the risk that a remedy will not succeed," and as a result, courts treat them skeptically. *See Kroger*, 2024 WL 5053016, at *26-28. The partial divestiture proposed by Defendants does not include the assets, personnel, or customer contracts to enable Integer to be an effective competitor and constraint on the merged firm. *See* PFOF, *supra* ¶ 141, 149-52, 154-61, 180-95.
- 313. In this inquiry, courts assess whether "customers will consider a post-merger [divestiture buyer] to be as capable of meeting their needs" as the competitor that exists today. *Sysco*, 113 F.Supp.3d at 74; *id.* at 77 (rejecting partial divestiture as insufficient in part because the divestiture buyer would "be at a competitive disadvantage in its ability to offer value-added services"). *Id.* at 77; *see* PFOF, *supra* ¶¶ 167, 207 (Integer would not have the same expertise/core competency).
- Defendants have touted *In the Matter of Boston Scientific / Guidant* (2006) as a successful partial divestiture that is similar to the proposed remedy. But that divestiture included an *entire* business line, including all customer contracts, which allowed the divestiture buyer to begin competing immediately. PX6092 at 003-004 (Decision and Order, *In the Matter of Boston Scientific/Guidant*) ("Assets to be Divested' means all of Respondent Guidant's assets, tangible and intangible, businesses and goodwill existing as of the Closing Date, that are related primarily to . . . the research, Development, manufacture, distribution, marketing or sale of Vascular Products, including . . . [IP, plants, technology, equipment, contracts, commitments, etc.]"); *see* PFOF, *supra*

 $^{^{538}}$ See PCOL, infra \P 314 and n. 539.

situation than the divesture at hand[.]"). 539

2. Integer's Past Experience Raises Concerns

315. A divestiture buyer's "history" in the relevant market may also "raise[] concerns about its ability to successfully compete following the divestiture" if the divestiture buyer has previously tried and failed to succeed in that market. *Aetna*, 240 F.Supp.3d at 72-73; *see Kroger*, 2024 WL 5053016, at *28 (assessing divestiture buyer's history in the relevant market). In *Aetna*, the court considered the divestiture buyer's past forays into the relevant market, none of which had succeeded, and found relevant that in those past attempts, the "company made a strategic decision" to exit the relevant market, particularly when the conditions for success had not changed. *Aetna*, 240 F.Supp.3d at 62, 73. Here, Integer's past failure to launch a differentiated product in the relevant market, and its business decision to abandon that effort, "raise concerns" about its ability to compete and innovate to offer new products in the future. *See* PFOF, *supra* ¶¶ 162-68.

3. Integer Will Not Be Independent from the Merged Firm

316. "[T]he independence of the divestiture buyer from the merging seller" is relevant to "whether a proposed divestiture will restore competition." *Kroger*, 2024 WL 5053016, at *24, 29. "In order to be accepted, curative divestitures must be made to a new competitor that is in fact . . . a willing,

That there have been some successful partial divestitures does not negate that partial divestitures are more likely to fail, nor do they show that this divestiture is likely to succeed. Moreover, unlike the proposed remedy, the cases Defendants identify *did* include divestiture of all assets and rights of full product lines and all corresponding revenue streams and customer contracts where applicable. *See, e.g., In the Matter of LindeAG / Praxair Inc.* (2019) (divestiture of multiple business lines and customer contracts, along with several facilities); *United States v. ASSA ABLOY* (2023) (divestiture of two branded businesses, including customer contracts); *In the Matter of AbbVie, Inc. / Allergan plc* (2020) (divestiture of two product lines and associated business); *In the Matter of Bristol-Myers Squibb Company / Celgene Corporation* (2019) (divestiture of worldwide Otezla business for \$13.4 billion). *See also* DOJ's proposed settlement in *United States v. UnitedHealth Group Inc. and Amedisys*, https://www.justice.gov/opa/media/1410291/dl, Aug. 7, 2025); *In the Matter of Danaher Corp. / General Electric, Co.* (2022); *In the Matter of ANI / Novitium* (2022); *In the Matter of Stryker / Wright Medical* (2020); *In the Matter of Pfizer / Mylan* (2020); *In the Matter of Teva / Allergan* (2016)); *In the Matter of Hikma Pharmaceuticals / Custopharm* (2022).

independent competitor capable of effective production in the . . . market." *CCC Holdings*, 605 F.Supp.2d at 59 (emphasis in original) (quotation omitted). "[I]t can be a problem to allow continuing relationships between the seller and buyer of divested assets after divestiture, such as a supply arrangement or technical assistance requirement, which may increase the buyer's vulnerability to the seller's behavior." *Sysco*, 113 F.Supp.3d at 77 (quotation omitted).

- 317. Continued entanglement with the merged firm includes, for example, the divestiture buyer being reliant on the merged firm for key inputs to its business. *See Kroger*, 2024 WL 5053016, at *29 (noting that merged firm, "a competitor, will provide sales forecasting data and a base pricing plan to [the divestiture buyer] for a period of time during the transition."); *Sysco*, 113 F.Supp.3d at 78-79 (finding that a divestiture was not a sufficient remedy in part because the divesture buyer would not be a "truly independent competitor" due to its reliance on the merged firm to license its products and services under a transition services agreement).
- 318. Courts have also noted with respect to transition services agreements between the merged firm and divestiture buyer, that the merged firm has "no incentive to provide any assistance beyond the bare minimum during this period, lest they create too powerful a competitor." *Aetna*, 240 F.Supp.3d at 71. Here, Integer will remain reliant on the merged firm for its new hydrophilic coatings supply business and for other critical inputs. *See* PFOF, *supra* ¶¶ 196-204.

4. The Low Purchase Price Raises Concerns

319. A low purchase price for a divestiture also "raises concerns about whether [the divestiture buyer] can be a successful competitor." *Aetna*, 240 F.Supp.3d at 72. "An extremely low purchase price reveals the divergent interest between the divestiture purchaser and the consumer: an inexpensive acquisition could still produce something of value to the purchaser even if it does not become a significant competitor and therefore would not cure the competitive concerns." *Aetna*, 240 F.Supp.3d at 72 (quotation omitted). In *Aetna*, for example, the court found it "more likely that [the

divestiture buyer] and its board moved forward with the divestiture because, for the price, it was low-risk and high-reward for the company, despite their belief that [the buyer] was not well positioned to be an effective competitor." *Id.* at 71. Here, Integer will acquire the divested assets for less than 10% of what GTCR paid for the full Biocoat business in 2022, PFOF, *supra* ¶¶ 141, 181, and Integer has incentives to make this acquisition that are unrelated to its ability to compete as an outsourced hydrophilic coatings supplier (such as using the coatings internally). *See* PFOF, *supra* ¶¶ 178-179.

b. Entry And Expansion Must Be Timely, Likely, and Sufficient to Counteract the Acquisition's Anticompetitive Effects

320. To rebut Plaintiffs' prima facie case, Defendants must demonstrate that expansion of existing firms or entry by new firms will be "timely, likely, and sufficient in its magnitude, character, and scope to deter or counteract the competitive effects" of the proposed acquisition. FTC v. Sanford Health, 926 F.3d 959, 965 (8th Cir. 2019); see also Kroger, 2024 WL 5053016 at *20 ("[D]efendant must demonstrate that it is sufficient to fill the competitive void that will result from the merger.") (quotations omitted). Courts have considered two years as a benchmark for whether expansion or entry is "timely." See CCC Holdings, 605 F.Supp.2d at 59 (citation omitted); see also Staples, 190 F.Supp.3d at 133; cf. Elders Grain, 868 F.2d at 905 (considering three-to-nine years for entry as "slow"). Moreover, "the mere fact that new entrants and fringe firms have an intent to compete does not necessarily mean that those firms are significant competitors capable of replacing lost competition." CCC Holdings, 605 F.Supp.2d at 59 (citation omitted). Here, the high entry barriers in the outsourced hydrophilic coatings market make it highly unlikely that entry or expansion by Integer or others will counteract the merger's anticompetitive effects. PFOF, supra ¶ 215-25.

c. Efficiencies Must Be Verifiable and Merger Specific

321. The Supreme Court has never recognized an efficiencies defense and "has instead, on three

occasions, cast doubt on its availability." *Penn. State Hershey Med. Ctr.*, 838 F.3d at 347) (collecting cases); *see also ProMedica*, 2011 WL 1219281, at *57 ("No court in a 13(b) proceeding, or otherwise, has found efficiencies sufficient to rescue an otherwise illegal merger."). Lower courts that have entertained the defense require that claimed efficiencies "offset the anticompetitive concerns in highly concentrated markets." *Penn. State Hershey Med. Ctr.*, 838 F.3d at 348. Courts also require that claimed efficiencies be "verifiable and merger-specific." *OSF Healthcare*, 852 F.Supp.2d at 1088; *H&R Block*, 833 F.Supp.2d at 89.

322. Critically, claimed efficiencies must "represent more than mere speculation and promises about post-merger behavior." *H&R Block*, 833 F.Supp.2d at 89 (quotations omitted); *see Univ. Health*, 938 F.2d at 1223 ("speculative, self-serving assertions" cannot overcome a "presumption of illegality"). Moreover, "[h]igh market concentration levels require proof of extraordinary efficiencies . . . and courts generally have found inadequate proof of efficiencies to sustain a rebuttal of the government's case." *OSF Healthcare*, 852 F.Supp.2d at 1088-89 (quotation omitted). Here, Defendants have not claimed any significant efficiencies, and any efficiencies are not merger specific, nor have they been independently verified. *See* PFOF, *supra* ¶ 226-27.

V. Equities Favor a Preliminary Injunction

323. In weighing the equities, the Seventh Circuit has instructed that "[i]t is always better to avoid relying on vague concepts and instead to ask concretely who would be helped and who hurt by a proposed action." *Elders Grain*, 868 F.2d at 903. Medical device companies, and ultimately patients, will be hurt by the elimination of competition in the market for outsourced hydrophilic coatings. Defendants have provided no evidence that the proposed acquisition will help any customer. Moreover, the public has strong interests in the effective enforcement of the antitrust laws and in preserving the FTC's ability to order effective relief if it succeeds after a trial on the merits. *Sysco*, 113 F.Supp.3d at 96-87 (citing *Heinz*, 246 F.3d at 726). Preliminarily enjoining a potentially

anticompetitive merger plainly serves those interests. *See FTC v. Warner Comm'cns*, 742 F.2d 1156, 1165 (9th Cir. 1984) ("A denial of preliminary injunction would preclude effective relief if the Commission ultimately prevails.").

- 324. "If the acquisition seems anticompetitive, then failing to stop it during the administrative proceedings will deprive consumers and suppliers of the benefits of competition pendente lite and perhaps forever, for it is difficult to undo a merger years after it has been consummated." *Elders Grain*, 868 F.2d at 904; *see also OSF Healthcare*, 852 F.Supp.2d at 1095 ("find[ing] significant that the difficulty of 'unscrambl[ing] merged assets' often precludes 'an effective [later] order of divestiture.") (quoting *FTC v. Dean Foods Co.*, 384 U.S. 597, 607 n.5 (1966)).
- 325. "When the Commission demonstrates a likelihood of ultimate success, a countershowing of private equities alone would not suffice to justify denial of a preliminary injunction barring the merger." *Elders Grain*, 868 F.2d at 903 (quotation omitted); *see also OSF Healthcare*, 852 F.Supp.2d at 1094 ("the FTC need not show any irreparable harm, and the private equities alone cannot override the FTC's showing of likelihood of success.") (quotation omitted). There is "no reason why, if the merger makes economic sense now, it would not be equally sensible to consummate the merger following [an] FTC adjudication on the merits that finds the merger unlawful." *Penn State Hershey Med. Ctr.*, 838 F.3d at 353. The only possible equity Defendants have pointed to in their favor is the interests of their investors. The equities here weigh strongly in favor of a preliminary injunction. PFOF, *supra* ¶ 228-30.

Dated: September 16, 2025

Of counsel:

DANIEL GUARNERA Director Bureau of Competition

DAVID J. SHAW Principal Deputy Director Bureau of Competition

JORDAN S. ANDREW Acting Assistant Director Mergers I Division

JAMES R. WEISS Deputy Assistant Director Mergers I Division Respectfully submitted,

/s/ Maia Perez MAIA PEREZ Lead Counsel Federal Trade Commission Bureau of Competition 600 Pennsylvania Avenue, NW Washington, DC 20580 Tel: (202) 326-3522 Email: mperez@ftc.gov

YAN GAO
R. TYLER SANBORN
EVELYN HOPKINS
DYLAN G. BROWN
WILLIAM M. MACCI
LAUREN GASKIN
ELIZABETH KLINGER
LILIANA P. VARGAS
NICHOLAS WIDNELL
MEGAN MCKINLEY
LILY VERBECK
LEONARDO CHINGCUANCO
JESSICA WEINER

Counsel for Plaintiff Federal Trade Commission

LE'ORA TYREE (IL Bar ID 6288669) Federal Trade Commission Midwest Regional Office 230 S. Dearborn Street, Room 3030 Chicago, IL 60604 Tel.: (312) 927-7660 Cell: (312) 960-5612

Local Counsel for Plaint

Email: ltyree@ftc.gov

Local Counsel for Plaintiff Federal Trade Commission

/s/ John Milligan

JOHN MILLIGAN

Assistant Attorney General

Office of the Illinois Attorney General 115

S. LaSalle Street, Floor 23

Chicago, IL 60603 Tel.: (773) 505-5937

Email: John.Milligan@ilag.gov

Counsel for Plaintiff State of Illinois

/s/ Elizabeth Odette

ELIZABETH ODETTE

Manager, Assistant Attorney General

Antitrust Division

Email: elizabeth.odette@ag.state.mn.us

/s/ Zach Biesanz

ZACH BIESANZ

Senior Enforcement Counsel Antitrust

Division

Email: zach.biesanz@ag.state.mn.us

Office of the Minnesota Attorney General

445 Minnesota Street, Suite 600

Saint Paul, MN 55101

Tel.: (651) 757-1257

Counsel for Plaintiff State of Minnesota

LOCAL RULE 37.2 CERTIFICATION

Pursuant to Local Rule 37.2, Plaintiffs Federal Trade Commission ("FTC" or "Commission") and the States of Illinois and Minnesota have met and conferred with Defendants GTCR, LLC, GTCR BC Holdings, LLC ("BC Holdings") and Surmodics, Inc. (collectively, "Defendants"). Defendants oppose the relief sought herein.

/s/ Maia Perez

Maia Perez
Jordan S. Andrew
James Weiss
Federal Trade Commission
Bureau of Competition
600 Pennsylvania Avenue, NW
Washington, DC 20580
Tel.: (202) 322-8971
Email: mperez@ftc.gov

Counsel for Plaintiff Federal Trade Commission

Le'Ora Tyree (IL Bar ID 6288669) Federal Trade Commission Bureau of Competition Midwest Regional Office 230 S. Dearborn Street, Room 3030 Chicago, IL 60604

Local Counsel for Plaintiff Federal Trade Commission

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 16th day of September, 2025, I filed the foregoing with the Clerk of the Court.

/s/ Maia Perez
Maia Perez
Attorney for Plaintiff Federal Trade Commission

Pursuant to Local Rule 5.9, I hereby certify that on this 16th day of September, 2025, the foregoing was electronically filed using the Court's CM/ECF system and constitutes service to the attorneys of record who have consented to accept service by electronic means and that GTCR, LLC's, GTCR BC Holdings, LLC's, and Surmodics, Inc.'s counsel of record are being served with a copy of this document via electronic mail.

<u>/s/ Maia Perez</u>

Maia Perez

Attorney for Plaintiff Federal Trade Commission